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Exhibit 339A

SETTLEMENT AND MEMORANDUM OF AGREEMENT

This Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice ("DOJ"), the United States Drug Enforcement Administration ("DEA"), and Walgreen Co. and its wholly owned subsidiaries ("Walgreens") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to Walgreens Corporate and any facility owned or operated by Walgreens that is or was registered with DEA to dispense, distribute, or otherwise handle controlled substances or List I chemicals. Unless explicitly stated herein, nothing contained in this Agreement will lessen, supplant or expand Walgreens' legal obligations under any statute, regulation, or law.

PROCEDURAL BACKGROUND

1. Walgreens owns or operates (or has previously owned or operated) distribution centers that are or were registered with DEA as distributors of Schedule II-V controlled substances under provisions of the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., ("CSA" or "the Act") (each a "Distribution Center," collectively the "Distribution Centers").

2. Walgreens owns or operates (or has previously owned or operated) pharmacies that are or were registered with DEA as Retail/Chain Pharmacies to handle Schedule II-V controlled substances under the CSA (each a "Pharmacy," collectively the "Pharmacies"). Walgreens owns or operates (or has previously owned or operated) Central Pharmacy Operations facilities that are or were registered with DEA as Retail/Chain Pharmacies or Central Fill Pharmacies to handle Schedule II-V controlled substances under the CSA (each a "CPO Facility," collectively the "CPO Facilities").

3. On April 7, 2011, Walgreens entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement with DEA. See Appendix A.

4. Walgreens' Jupiter Distribution Center ("Walgreens Jupiter") is registered with DEA as a distributor of Schedule II-V controlled substances at 15998 Walgreens Drive, Jupiter, Florida 33478 (Registration RW0277752).

5. On September 13, 2012, the DEA, by its Administrator, Michele M. Leonhart, issued an Order to Show Cause and Immediate Suspension of Registration ("OTSC/ISO") to Walgreens Jupiter. See Appendix B. After Walgreens requested an administrative hearing before DEA, the Administrative Law Judge ("ALJ") docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-1.

6. On November 26, 2012, the DEA, by its Deputy Assistant Administrator, Joseph T. Rannazzisi, issued three OTSCs to Walgreens Retail Pharmacy (1) #03629, 12028 Majestic Boulevard, Hudson, Florida 34667 (Registration BW4713992); (2) #04727, 4950 South U.S. Highway 1, Fort Pierce, Florida 34952 (Registration BW6561270); and

(3) #06997, 785 Lockwood Boulevard, Oviedo, Florida 32765 (Registration BW8487438). See Appendix C. After Walgreens requested an administrative hearing on each of these three matters, the ALJ docketed each case, *In the Matter of Walgreen Co.*, respectively Docket Nos. 13-9, 13-10, and 13-11.

7. On February 4, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens Retail Pharmacy #03836, 9332 U.S. Highway 19, Port Richey, Florida 34668 (Registration AW8830247). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-16.

8. On February 11, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #04391, 2501 Virginia Avenue, Fort Pierce, Florida 34981 (Registration BW5872494). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-18.

9. Finally, on February 19, 2013, the DEA, by Deputy Assistant Administrator Rannazzisi, issued an OTSC to Walgreens #03099, 1525 Colonial Boulevard, Fort Myers, Florida 33907 (Registration AW1366877). See Appendix C. After Walgreens requested an administrative hearing, the ALJ docketed the case, *In the Matter of Walgreen Co.*, Docket No. 13-20.

10. On February 22, 2013, the ALJ consolidated the seven cases into one consolidated proceeding that was scheduled for an Administrative Hearing initially on January 7, 2013, and then continued until February 25, 2013, and again until April 23, 2013.

STIPULATION AND AGREEMENT

The facts alleged in the OTSC/ISO issued to Walgreens Jupiter, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1, as listed in Appendix B, would, if proven, constitute grounds under which DEA could revoke the DEA registration of Walgreens Jupiter. The facts alleged in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, as well as the facts alleged in the government's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, would, if proven, constitute grounds under which DEA could revoke the DEA registrations of Walgreens #03629, #04727, #06997, #03836, #04391, and #03099.

Walgreens acknowledges that suspicious order reporting for distribution to certain pharmacies did not meet the standards identified by DEA in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Walgreens, on September 27, 2006, February 7, 2007 and December 27, 2007. Furthermore, Walgreens acknowledges that certain Walgreens retail pharmacies did on some occasions dispense certain controlled substances in a manner not fully consistent with its compliance obligations under the CSA (21 U.S.C. §§ 801 et seq.) and its implementing regulations (21 C.F.R. Part 1300 et seq.). Finally, Walgreens acknowledges that its

recordkeeping practices regarding the dispensing of controlled substances from certain retail pharmacies utilizing its CPO Facilities as central-fill pharmacies did not require such original prescriptions to be marked "CENTRAL FILL."

Walgreens, DEA, and DOJ agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement in these administrative matters is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority and civil penalty matters arising under the CSA and its implementing regulations relating to (1) the conduct described in the OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket No. 13-1; (2) the conduct described in the OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20; (3) recordkeeping obligations of the CPO Facilities and Pharmacies; (4) other allegations regarding Covered Conduct identified in Section I.2 of this Agreement involving any other Walgreens DEA registrant; and (5) any other allegations relating to conduct arising under the CSA or its implementing regulations which DEA or DOJ knows or has reason to know of as of the effective date of this Agreement, regardless of whether DEA or DOJ has notified Walgreens of such allegations, including conduct at any Walgreens registrant where DEA or DOJ has an open investigation. This includes the open civil investigation into the above-referenced conduct in the United States Attorney's Office for the Southern District of Florida, as well as open civil investigations in the United States Attorney's Offices for the District of Colorado, the Eastern District of Michigan, and the Eastern District of New York. This also includes civil investigations by DEA Field Offices nationwide. The Parties further believe that the terms and conditions of this Agreement as set forth below represent a complete resolution of these matters.

2. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following, whether it occurred at a specific Walgreens DEA registrant or elsewhere within Walgreens:

   a. Distribution Centers

      (1) Conduct alleged in the September 13, 2012 OTSC/ISO issued to Walgreens Jupiter, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket 13-1, as listed in Appendix B, and similar allegations regarding any other Walgreens Distribution Center, occurring on or before the effective date of this Agreement;

      (2) Failure regarding any Distribution Center to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific and industrial channels, as required by 21 U.S.C. §§

823(b) and (e), including any failures to conduct adequate due diligence to ensure that controlled substances were not diverted into other than legitimate channels, on or before the effective date of this Agreement;

(3) Failure regarding any Distribution Center to timely detect and report suspicious orders of controlled substances as required by 21 U.S.C. § 823 and/or 21 C.F.R. § 1301.74(b) on or before the effective date of this Agreement;

(4) Distributing controlled substances to pharmacies by any Distribution Center that the Distribution Center knew or should have known were engaged in any of the Covered Conduct listed in Section I.2.b of this Agreement on or before the effective date of this Agreement;

(5) Failure regarding any Distribution Center to make complete and accurate ARCOS reports, on or before the effective date of this Agreement;

(6) Refusal or negligent failure by any Distribution Center to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, on or before the effective date of this Agreement; and

(7) Conduct regarding any Distribution Center inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement.

b. Walgreens Pharmacies and CPO Facilities

(1) Conduct alleged in the November 26, 2012, February 4, 2013, February 11, 2013, and February 19, 2013 OTSCs issued to Walgreens #03629, #04727, #06997, #03836, #04391, and #03099, and in DEA's filings in *In the Matter of Walgreen Co.*, Docket Nos. 13-9, 13-10, 13-11, 13-16, 13-18, and 13-20, as listed in Appendix C, and similar allegations regarding any other Walgreens Pharmacy or CPO Facility, occurring on or before the effective date of this Agreement;

(2) Failure of Walgreens Pharmacists at any Pharmacy or CPO Facility to exercise their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a), and dispensing by any Pharmacy, or CPO Facility, of controlled substances pursuant to purported prescriptions that were otherwise invalid under 21 C.F.R. Part 1306, on or before the effective date of this Agreement;

(3) Dispensing by any Pharmacy or CPO Facility of controlled substances to individuals Walgreens knew or should have known were diverting controlled substances on or before the effective date of this Agreement;

(4) Dispensing by any Pharmacy or CPO Facility of controlled substances pursuant to prescriptions issued by a physician who did not have a current, valid DEA registration on or before the effective date of this Agreement;

(5) Refusal or negligent failure by any Pharmacy or CPO Facility to make, keep, or furnish any record, report, notification, declaration, order or order form, statement, invoice, or information required under the CSA and its implementing regulations, including, but not limited to, failure by any Pharmacy or CPO Facility to maintain accurate records pursuant to 21 C.F.R. Part 1304 and to properly label and/or mark prescriptions pursuant to 21 C.F.R. Part 1306, on or before the effective date of this Agreement;

(6) Conduct inconsistent with the CSA and its implementing regulations on or before the effective date of this Agreement, by any Pharmacy or CPO Facility; and

(7) Failure by any Walgreens registrant, including any Pharmacy or CPO Facility, to adhere to the provisions of the April 7, 2011 Administrative Memorandum of Agreement between Walgreen Co. and DEA (the "2011 MOA").

3. Effect of 2011 MOA. The obligations contained in the 2011 MOA are superseded by the obligations contained within this Agreement.

4. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of three (3) years from the effective date of this Agreement unless the Parties agree in writing to an earlier termination, provided, however, that the releases in Paragraphs II.6 and II.8 in this Agreement extend beyond the effective date.

II. Terms and Conditions

1. Obligations of Walgreens Distribution Centers.

a. Walgreens will continue to review, and where reasonable and appropriate, to revise its processes and practices for conducting suspicious order monitoring and reporting suspicious orders from Walgreens' pharmacies, as set forth in the attached Addendum.

b. Walgreens shall inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b) in a format mutually and reasonably agreed upon by the Parties.

c. Walgreens agrees to the surrender of Walgreens Jupiter's DEA Registration RW0277752 for controlled substances Schedules II-V, until September 13, 2014.

2. Obligations of Walgreens Pharmacies and CPO Facilities.

a. Walgreens agrees to maintain a compliance program in an effort to detect and prevent diversion of controlled substances as required under the CSA and applicable DEA regulations, as set forth in the attached Addendum. This program shall include procedures to identify the common signs associated with the diversion of controlled substances. The program shall also include the routine and periodic training of all Walgreens pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA and applicable DEA regulations. This compliance program shall apply to all Walgreens Pharmacies and CPO Facilities.

b. Walgreens shall implement and maintain policies and procedures in an effort to ensure that prescriptions for controlled substances are only dispensed to authorized ultimate users pursuant to federal and state law and regulations. Walgreens shall maintain its current policy that requires all customers to provide identifying information and shall also require valid photo identification as required by and in accordance with controlling state law where the pharmacy is located. Documents maintained by Walgreens pursuant to any obligation under federal and/or state law regarding the verification of an ultimate user's identity shall be kept readily available by the pharmacy, and shall be produced to DEA agents, task force officers or investigators on request.

c. Walgreens shall direct and train its pharmacists that their corresponding responsibility under federal law requires them not to fill a prescription that such pharmacist knows or has reason to know was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice.

d. In connection with Walgreens' recordkeeping obligations, Walgreens agrees to maintain records regarding the dispensing of controlled substances in electronic format, in addition to the regularly maintained paper files, including records relating to which Distribution Center and/or CPO Facility shipped the controlled substance to the Pharmacy. These records shall be made available to DEA agents, task force officers or investigators, upon demand, without the need for a warrant or subpoena, provided that the DEA agents, task force officers or investigators present appropriate identification. Walgreens shall provide electronic reports of dispensing on an ad hoc basis in response to DEA requests within a reasonable time.

e. Walgreens agrees to the surrender of the DEA registrations to dispense controlled substances for Schedules II-V at the following facilities until May 26, 2014: BW4713992 (#03629), BW6561270 (#04727), BW5872494 (#04391), AW8830247 (#03836), AW1366877 (#03099), and BW8487438 (#06997).

3. Walgreens General Obligations.

a. Walgreens' policy and procedure is to cooperate with the government in any investigation. Walgreens agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other law enforcement agency investigating or prosecuting customers of Walgreens' pharmacies for alleged violations or activities related to the Covered Conduct, unless such matters would affect the rights or obligations of Walgreens in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews as reasonable and appropriate with reasonable notice in advance. However, nothing in this paragraph shall be construed as a waiver by Walgreens, its directors, officers or employees of any constitutional rights or rights that they would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

b. Walgreens agrees that it will promptly move to dismiss, with prejudice, the pending lawsuit by Walgreens in Case No. 12-1397 in the United States Court of Appeals for the District of Columbia Circuit.

c. Walgreens agrees to pay the United States eighty million dollars ($80,000,000.00) ("the Settlement Amount") within ten (10) days of the effective date of this Agreement by electronic funds transfer pursuant to written instructions provided to Walgreens by the United States Attorney's Office for the Southern District of Florida.

4. Obligations of DEA.

a. DEA agrees to accept at DEA Field Offices the information regarding suspicious orders as required under 21 C.F.R. § 1301.74(b) in the manner described in the attached Addendum.

b. Within five (5) business days of the effective date of this Agreement, DEA agrees to unlock the controlled substances storage area at Walgreens Jupiter and make its contents available to Walgreens for any lawful transfer or reverse distribution of the inventory contained therein to an appropriate DEA registrant(s).

c. Provided that Walgreens submits a re-application for each of the above-listed facilities at least four (4) months prior to the end of the applicable surrender period, DEA agrees that, upon application by Walgreens, it will grant (1) a DEA registration to distribute controlled substances in Schedules II-V for Walgreens Jupiter on or before September 13, 2014, and (2) DEA registrations to dispense controlled substances in Schedules II-V for the Walgreens Pharmacies listed in Paragraph II.2.e on or before May 26, 2014.

5. Joint Obligations of the Parties.

   a. Walgreens and DEA agree that upon the execution of this Agreement, DEA and Walgreens shall promptly file a joint motion with the ALJ to terminate all pending administrative proceedings against Walgreens.

6. Release by the United States. In consideration of the fulfillment of the obligations of Walgreens under this Agreement, the United States agrees to:

   a. Release Walgreens and all Walgreens facilities, including Walgreens subsidiary entities, affiliates, and registrants, along with their respective officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any administrative claims related to Covered Conduct prior to the effective date of this Agreement within DEA's enforcement authority under the CSA and its implementing regulations, and any corresponding DOJ authority for civil penalty claims under 21 U.S.C. § 842.

   b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under the CSA and its implementing regulations based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement; and

   c. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct, or other noncompliant conduct to the extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of investigations and inspections in existence as of the effective date of this Agreement, or the review of the reports and records Walgreens submitted to DEA prior to the effective date of this Agreement.

7. Notwithstanding the releases by the United States in Paragraph #6 above, DEA reserves the right to seek to admit evidence of Covered Conduct for proper evidentiary purposes in any future administrative proceeding against Walgreens for non-Covered Conduct. Further, nothing in this Agreement shall prohibit or limit any other agency within DOJ, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiated an investigation, action, or proceeding involving Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any component of DOJ, based on the Covered Conduct. At Walgreens' request, DEA and DOJ agree to disclose the terms of this Agreement to any other agency and will represent, assuming

Walgreens is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed.

8. Release by Walgreens. Walgreens fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Walgreens has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

9. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Walgreens) are the following:

   a. Any potential criminal liability;

   b. Any civil, criminal or administrative liability arising under Title 26, United States Code (Internal Revenue Code); or

   c. Any liability based upon such obligations as are created by this Agreement.

   d. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the settlement amount for purposes of the Internal Revenue Laws, Title 26 of the United States Code.

10. Walgreens agrees that any and all costs it has or will incur in connection with this matter—including payment of the Settlement Amount under this Agreement, attorney's fees, costs of investigation, negotiation, and remedial action—shall be unallowable costs for government contracting accounting and for Medicare, Medicaid, TriCare, and FEHBP (or any other government reimbursement program) for reimbursement purposes.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on Walgreens, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Parties.

4. Incorporation of Addendum. This Agreement incorporates a separate document, entitled "Addendum: Prospective Compliance," containing additional compliance measures to be undertaken by Walgreens.

5. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties.

   Walgreens represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Walgreens further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

6. Execution of Agreement. This Agreement shall become effective on the date of signing by the last signatory (the "Effective Date"). The United States agrees to notify Walgreens immediately when the final signatory has executed this Agreement.

7. Notices. All communications and notices to Walgreens pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by Walgreens providing written notification to DEA:

   a. Dwayne A. Piñon, Director, Pharmacy Law, Operations & Services, Walgreen Co., 104 Wilmot Road, MS #1434, Deerfield, Illinois 60015; fax: 847-315-4660; email: dwayne.pinon@walgreens.com.

8. Disclosure. Walgreens and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

9. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement.

10. Authorizations. The individuals signing this Agreement on behalf of Walgreens represent and warrant that they are authorized by Walgreens to execute this Agreement. The individuals signing this Agreement on behalf of DEA and DOJ represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA and DOJ to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and any Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties relating to this Agreement will be the United States District Court or, as appropriate, in the Court of Federal Claims, in which the Walgreens facilities and/or registrations at issue are located. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA.

IN WITNESS WHEREOF, the Parties hereto have duly executed this Memorandum of Agreement.

On Behalf of Walgreen Co.:

Thomas J. Sabatino
Executive Vice President, General Counsel and Corporate Secretary
Walgreen Co.

Dated: 6/10/13

Alice S. Fisher
Philip J. Perry
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004
Counsel for Walgreen Co.

David S. Weinstein
Clarke Silverglate, P.A.
799 Brickell Plaza
Suite 900
Miami, FL 33131
Counsel for Walgreen Co.

Dated: June 10, 2013

On Behalf of the United States Department of Justice:

Wifredo A. Ferrer
United States Attorney
Southern District of Florida

Dated: 6/11/13

Franklin G. Monsour, Jr.
Assistant United States Attorney
Southern District of Florida

Dated: 6/11/13

On Behalf of the United States Drug Enforcement Administration:

Michele M. Leonhart
Administrator
United States Drug Enforcement Administration

Dated: 6/10/13

Addendum: Prospective Compliance

The Parties agree that Walgreens will maintain the following specific compliance measures for the duration of this Agreement. To the extent any compliance measures identified below are not yet in place, Walgreens commits to implement such measures within the timeframes specified herein.

A. General

1. Walgreens will maintain a Department of Pharmaceutical Integrity, composed of personnel with pharmacy-related training and managerial personnel, who shall be trained in relevant diversion-related issues, to coordinate compliance efforts related to controlled substances. Within one (1) month of the effective date of this Agreement, Walgreens will identify a dedicated contact point (including a dedicated email address) for DEA within the Department of Pharmaceutical Integrity to facilitate Walgreens' responses to DEA requests for information and documents, specifically including responses to requests for dispensing log data and pseudoephedrine data.

B. Pharmacies

1. Upon request by DEA to Walgreens' Department of Pharmaceutical Integrity, within two (2) business days Walgreens will provide to DEA, via appropriate secure means of electronic transmission, controlled substance dispensing logs consisting of those categories of information the regulations require dispensers to maintain as records, *see* 21 C.F.R. § 1304.22(c). DEA understands and agrees that additional reasonable time may be required to the extent DEA seeks additional data or information not regularly maintained for such logs.

2. For all Schedule II controlled substance prescriptions, Walgreens currently affixes a sticker to each paper prescription containing certain dispensing information such as: a serial number unique to each prescription (which includes a suffix identifying the dispensing retail pharmacy); the prescriber's name, address, telephone number, and DEA registration number; the patient's name, address, and telephone number; the prescription issue date; the drug and quantity dispensed; and the fill date. Walgreens currently also affixes such stickers to Schedule III-V controlled substance paper prescriptions in certain states, but not others, depending upon state law requirements. Within three (3) months of the effective date of this Agreement, Walgreens pharmacies will affix such a sticker to all paper controlled substance prescriptions in each state, regardless of the requirements of state law. Walgreens will maintain a paper file of such prescriptions organized chronologically by fill date. In the event that DEA requests an electronic list of such prescriptions in sequential order by prescription number, Walgreens' Department of Pharmaceutical Integrity will provide such a list upon request within a reasonable time. Paper prescriptions will be maintained at the registered location of the pharmacy that dispensed them for a period of the longer of two (2) years or that required by applicable state law.

3. Walgreens' retail pharmacies utilize a computer application for the storage and retrieval of refill information for original paper prescriptions. For prescription refills, Walgreens will follow the procedures outlined in 21 C.F.R. § 1306.22(f). To the extent that DEA wishes to retrieve electronic records regarding refills, Walgreens' Department of Pharmaceutical Integrity will facilitate responses to such requests, including by providing such information to DEA upon request in a manner that is sortable and retrievable by prescriber name, prescriber DEA registration number, patient name, patient address, drug dispensed, date filled, and last name of dispensing pharmacist.

4. Walgreens remains committed to properly training its pharmacy personnel to deal with evolving diversion-related issues. Walgreens will continue to enhance its Good Faith Dispensing Policy and training materials to identify "red flags" of potential diversion for pharmacists to consider in making professional judgments regarding dispensing of controlled substances. Walgreens will train its pharmacy personnel at least annually on Good Faith Dispensing and will update the Good Faith Dispensing Policy and training materials to respond to changing diversion threats of which Walgreens is aware. DEA will share information with Walgreens periodically regarding circumstances that may present "red flags" of potential diversion. Walgreens' training program will also instruct pharmacists and supervisory personnel to contact the Department of Pharmaceutical Integrity, as appropriate, to address specific problematic issues arising with particular patients or physicians, so that the Department of Pharmaceutical Integrity can assess and respond to such issues. Pharmacist training will also cover instruction on how to assist DEA in obtaining records as required by this Agreement or any regulations.

5. Walgreens will maintain procedures to verify that the DEA registration number for the issuing prescriber of a controlled substance is a current, valid registration number. Such verification shall be performed using information from the National Technical Information Service (NTIS) database or similarly reliable third party database where DEA registration changes are recorded. Walgreens agrees to maintain a system integrating NTIS data with Walgreens' computer system that will: (1) update NTIS registration data on a weekly basis; and (2) prevent a pharmacy from filling a controlled substance prescription using a registration number not listed in such NTIS data until such prescriber's valid registration number is confirmed.

6. Beginning in 2014, Walgreens will exclude any accounting for controlled substance prescriptions dispensed by a particular pharmacy from bonus computations for pharmacists and pharmacy technicians at that pharmacy.

7. For each retail pharmacy, Walgreens will maintain, either electronically or in paper form, a log of pseudoephedrine purchases that can be made available upon request to authorized DEA personnel. To the extent that printing or copying of such a log from electronic records at a pharmacy would be unduly laborious or time-consuming, DEA agrees that Walgreens' Department of Pharmaceutical

Integrity will facilitate transmission of such information, including through transmission of electronic records to DEA.

C. Distribution Centers

1. Within one (1) week of the effective date of this Agreement, Walgreens will designate a DEA contact point in its Department of Pharmaceutical Integrity to address inquiries regarding suspicious order monitoring and reporting. At least one (1) existing employee at each Walgreens distribution center that distributes controlled substances will receive appropriate training on suspicious order monitoring requirements and on reporting relevant issues to the Department of Pharmaceutical Integrity.

2. For purposes of complying with suspicious order monitoring and reporting requirements for orders to be supplied by a Walgreens distribution center, Walgreens will maintain the tolerance threshold, ceiling limits, and other elements of its current suspicious order monitoring and reporting system, either for the duration of this Agreement or until Walgreens distribution activities are transitioned to a third party. Walgreens will endeavor to conduct its evaluations of "orders of interest" identified by its tolerance thresholds and ceiling limits within four (4) business days in most cases, and shall inform DEA Field Offices of orders that Walgreens has determined are "suspicious" within two (2) business days of making any such determination. Walgreens agrees not to ship any "order of interest" or "suspicious order" in whole or in part unless and until Walgreens resolves the reason(s) that caused it to designate the order as an "order of interest" or a "suspicious order." Within ninety (90) days of the effective date of this Agreement, suspicious order reports shall identify reason(s) an order was determined to be suspicious, and the registration number for the specific Walgreens distribution center that would have received the order at issue.

3. Within eighteen (18) months of the effective date of this Agreement, Walgreens will initiate enrollment in and operationally implement DEA's Controlled Substance Ordering System (CSOS) for orders of all Schedule II controlled substances placed by its retail pharmacies to its distribution centers.

APPENDIX A

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration (hereinafter "DEA") and Walgreen Co., on its behalf as well as on behalf of its subsidiaries that operate walk-in, retail pharmacies under the name Walgreens (hereinafter "Walgreens") (each a "Party" and collectively hereinafter referred to as the "Parties").

I. APPLICABILITY

This Agreement shall be applicable to all current and future Walgreens walk-in, retail pharmacy locations registered with the DEA to dispense controlled substances.

II. BACKGROUND

On September 30, 2009, the Deputy Assistant Administrator, Office of Diversion Control, DEA, issued an Order to Show Cause ("OTSC"), proposing to revoke DEA Certificate of registration BW8002759 of Walgreens #06094 located at 3005 Midway Drive, San Diego, California 92110.

The OTSC alleged that Walgreens #06094 (1) dispensed controlled substances to individuals based on purported prescriptions issued by physicians who were not licensed to practice medicine in California; (2) dispensed controlled substances to individuals located in California based on Internet prescriptions issued by physicians for other than a legitimate medical purpose and/or outside the usual course of professional practice in violation of federal and state law; and (3) dispensed controlled substances to individuals that Walgreens #06094 knew or should have known were diverting the controlled substances. See Appendix A (OTSC dated September 30, 2009). In addition to the allegations raised in the OTSC, DEA's investigation also reveals that Walgreens #06094 was allegedly refilling prescriptions for controlled substances too early and had allegedly filled several prescriptions that were issued using expired DEA registration numbers.

The OTSC was served via Certified Mail, Return Receipt Requested on October 5, 2009. On October 26, 2009, Walgreens #06094, through counsel, filed a hearing request with the Administrative Law Judge, wherein Walgreens #06094 generally disputed the factual allegations of the OTSC and disagreed with DEA's position that the DEA registration of Walgreens #06094 should be revoked. See Appendix B (Request for Hearing dated October 26, 2009).

The facts alleged above and in the OTSC could, if proven at hearing, constitute a basis to revoke the DEA registration of Walgreens #06094. The Parties, however, desire to settle the administrative matter pending against Walgreens #06094. Moreover, the Parties believe that the continued cooperation between the Parties to reduce the potential for diversion is in the public interest and entering into this Agreement will ensure nationwide compliance by Walgreens with respect to its pharmacy operations.

In consideration of the mutual covenants and agreements contained herein, and for other good and valuable consideration, and intending to be legally bound hereby, the Parties hereto agree as follows:

III. TERMS AND CONDITIONS

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, the Parties agree to resolve this matter according to the Terms and Conditions below.

2. No Admission or Concession. This Agreement is neither an admission by Walgreens of liability or of any allegations made by DEA in the OTSC and its investigation of Walgreens Pharmacy #06094, nor a concession by DEA that its allegations in the OTSC and its investigation of Walgreens Pharmacy #06094 are not well-founded.

3. Covered Conduct for Purposes of this Agreement. "Covered Conduct" shall mean the conduct alleged in the OTSC and described in Section II of this Agreement against Walgreens #06094.

4. Obligations of Walgreens:

   a. Walgreens agrees to maintain a compliance program to detect and prevent diversion of controlled substances as required under the Controlled Substances Act ("CSA") and applicable DEA regulations. This program shall include procedures to identify the common signs associated with the diversion of controlled substances including but not limited to, doctor-shopping and requests for early refills. The program shall also include the routine and periodic training of all Walgreens walk-in, retail pharmacy employees responsible for dispensing controlled substances on the elements of the compliance program and their responsibilities under the CSA. This compliance program shall apply to all current and future Walgreens walk-in, retail pharmacies registered with the DEA in the United States and its territories and possessions.

   b. Walgreens shall implement a system to notify the local DEA office within two business days of a refusal to fill a prescription for controlled substances where such refusal is based on the Walgreens pharmacist's determination that the prescription was forged, altered, and/or issued for other than a legitimate medical purpose by a practitioner acting outside the usual course of professional practice. However, in no case shall Walgreens be required to maintain a record of such refusals. An unintentional failure to meet the two-day notification deadline shall not be deemed a material breach of this Agreement.

   c. Walgreens shall implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations. Walgreens shall maintain its current policy that requires all customers to provide identifying information such as name, date of birth and/or address when picking up a prescription and shall also require individuals obtaining prescriptions for controlled substances to present valid photo identification as required by and in accordance with controlling state law where the pharmacy is located. Walgreens shall also annotate the prescription file or other record to document the type of identification presented and the number, if any, associated with the identification, if required by state law. Documents maintained by Walgreens pursuant to any obligation under applicable state law regarding the verification of an ultimate user's identity shall be

readily retrievable by the pharmacy, and shall be produced to DEA agents, task force officers or investigators upon request.

d. Walgreens shall not knowingly fill an invalid prescription or a prescription that it reasonably believes was issued for other than a legitimate medical purpose or by a practitioner acting outside the usual course of professional practice. Walgreens shall comply with state law with regard to dispensing controlled substances based on a prescription written by a prescriber located outside of the state where the patient and pharmacy are located. Walgreens pharmacists shall comply with state law, if applicable, and, where circumstances lead the pharmacist in his or her professional judgment to reasonably doubt the validity of the prescription, verify that a valid prescriber/patient relationship exists before filling a prescription for a controlled substance.

e. Walgreens shall implement procedures to verify that the DEA registration number for the issuing prescriber of each controlled substance prescription is a valid, active DEA registration number, independent of calling the local DEA office. Such verification shall be performed periodically using the NTIS or similarly-reliable third-party database where DEA registration changes are recorded. Walgreens is not precluded from contacting any DEA office to verify the legitimacy of a DEA registration, however, it is understood that verification of a DEA number does not fulfill all of the obligations of a pharmacist's corresponding responsibility.

f. In connection with Walgreens' record keeping requirements pursuant to 21 C.F.R. § 1304, Walgreens agrees to maintain records regarding the dispensing of controlled substances in electronic format, in addition to the regularly-maintained, official paper files. These records shall be made available to DEA agents, task force officers or investigators, upon demand, without the need for a warrant or subpoena, provided that the DEA agents, task force officers or investigators present an appropriate form of identification. Walgreens shall provide electronic reports of dispensing on an ad hoc basis in response to requests by DEA within a reasonable time. The paper records shall continue to be the official record and shall be consulted when there is any question as to the accuracy of the electronic records.

g. All dispensing records submitted by Walgreens to Prescription Monitoring Programs (PMPs) (in those states that have or will implement such a system) shall, to the extent required under applicable state law, contain a prescriber's valid, active DEA registration number. Such information submitted to state Prescription Monitoring Programs shall be extracted from Walgreens' electronic records of dispensing, which shall be available for review by DEA agents, task force officers or investigators.

h. Walgreens shall provide pharmacists with access to state PMPs and pharmacists shall be required to follow state guidelines and requirements for use and review of information provided by the state PMP on dispensing controlled substances. It is agreed and understood that the pharmacist is ultimately responsible to use his or her professional judgment on whether the information will be useful in determining the appropriateness of filling a prescription for a controlled substance.

i. Walgreens shall maintain a system to only dispense refills of controlled substances in schedules III – V that are valid and appropriately-authorized. Within six months of execution of this Agreement, Walgreens shall also implement a system to identify and prevent early refills of controlled substances for all cash payments of controlled substances. A pharmacist who, in the exercise of his/her professional judgment determines that a prescription may be refilled early must do so consistent with federal and state laws, regulations or guidelines and provide a reasonable explanation for the early refill. Walgreens shall maintain records regarding the pharmacist's rationale for dispensing such early refill in a manner consistent with other records required to be kept by the pharmacy. These records shall be readily retrievable by the pharmacy and shall be produced to DEA agents and/or investigators upon demand.

j. Walgreens currently maintains cameras at every walk-in retail pharmacy, which capture images of the front door and/or the pharmacy counters. Walgreens shall continue to maintain all currently-installed security cameras in these locations. Walgreens understands and takes seriously the need for security in its locations, and will continue to monitor security and make modifications as needed to maintain store security. Walgreens shall implement and maintain procedures to retain recordings from security cameras for at least 30 days. These recordings shall be readily retrievable at pharmacy locations, and shall be produced to DEA agents and/or DEA investigators upon request. To the extent a particular pharmacy's security camera has the technical capability to record beyond the required 30-day period, Walgreens shall endeavor to produce such additional recordings upon request. Nothing in this paragraph, however, shall be construed to require Walgreens to maintain any camera recording beyond the 30-day period described herein.

k. Walgreens shall report to the local DEA office, within twenty calendar days after discovery, the initiation of any adverse legal proceeding relating to its pharmacy permit, license or registration, that is known to Walgreens, and is conducted or brought by a government entity or licensing board regarding the dispensing of controlled substances or sale of scheduled listed chemical products.

5. Release by DEA. In consideration of the fulfillment of the obligations of Walgreens under this Agreement, DEA hereby releases and agrees to refrain from filing any administrative actions against Walgreens' DEA registrations based on the Covered Conduct or similar conduct at any other Walgreens pharmacy on or before the effective date of this agreement, within DEA's enforcement authority under 21 U.S.C. §§ 823 and 824. Notwithstanding the release by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct in any other administrative proceedings. Further, nothing in this Paragraph shall prohibit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State or political subdivision thereof ("law enforcement agency"), from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any law enforcement agency that initiates an investigation, action, or proceeding, involving the Covered Conduct. At Walgreens' request, DEA agrees to disclose the terms of this

Agreement to any other law enforcement agency and will represent that Walgreens' compliance with this Agreement adequately addressed the allegations raised in the administrative proceedings by DEA as defined in the Covered Conduct.

6. Release by Walgreens. Walgreens fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which Walgreens has asserted, could have asserted, or may assert in the future against the United States of America, its agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including Walgreens) are the following:

   a. Any civil, criminal, or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

   b. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct subject to paragraph 5 of the Agreement;

   c. Any liability based upon such obligations as are created by this Agreement.

8. Binding on Successors. This Agreement shall inure to the benefit of and is binding on Walgreens, and its respective successors, heirs, transferees and assigns.

9. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

10. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and Released Parties only and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

11. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the Parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. Walgreens represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. Walgreens further represents that this Agreement is voluntarily entered into in order to avoid litigation, without duress or compulsion.

12. Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"), and remain in effect for a period of three years from the Effective Date. DEA agrees to notify Walgreens immediately when the final signatory has executed this Agreement.

13. Breach of Agreement. Only material and systemic violations of the provisions of this Agreement may constitute a breach of the agreement. Parties shall have a reasonable time to cure any such violation.

14. Effect of Breach. A material breach shall render the Agreement voidable; however, such breach may be waived by the Parties.

15. Disclosure. Walgreens and DEA may each disclose the existence of this Agreement and information about this Agreement to the public without restriction.

16. Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which constitute one and the same agreement.

17. Authorizations. The individuals signing this Agreement on behalf of Walgreens represent and warrant that they are authorized by Walgreens to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

THE UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION

JOSEPH T. RANNAZZISI
Deputy Assistant Administrator
Office of Diversion Control

Dated: 4/7/11

WENDY H. GOGGIN
Chief Counsel

Dated: 4/1/11

WALGREEN CO.

RICHARD ASHWORTH
Divisional Vice President, Pharmacy Services
Walgreen Co.

Dated: 3/18/2011

JOHN A. GILBERT, JR
Hyman, Phelps & McNamara, PC
Attorney for Walgreen Co.

Dated: 3/28/11

APPENDIX B

U.S. Department of Justice
Drug Enforcement Administration

Office of the Administrator

Springfield, VA 22152

September 13, 2012

IN THE MATTER OF

Walgreen Co.
15998 Walgreens Drive
Jupiter, Florida 33478

ORDER TO SHOW CAUSE AND
IMMEDIATE SUSPENSION OF REGISTRATION

PURSUANT to Sections 303 and 304 of the Controlled Substances Act, Title 21, United States Code, Sections 823 and 824,

NOTICE is hereby given to inform Walgreen Corporation ("Walgreens" or "Respondent") of the immediate suspension of Drug Enforcement Administration ("DEA") Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(d), because such registration constitutes an imminent danger to the public health and safety. Notice is also given to afford Walgreens an opportunity to show cause before DEA in Arlington, Virginia, or a location designated by the Administrative Law Judge, on November 13, 2012 (if Walgreens requests such a hearing), as to why DEA should not revoke Walgreens's DEA Certificate of Registration RW0277752, pursuant to 21 U.S.C. § 824(a)(4), deny any pending applications for renewal or modification of such registration, and deny any applications for additional registration, pursuant to 21 U.S.C. § 823(b) & (e), because Walgreens' continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. § 823(b) & (e). The basis for this Order to Show Cause and Immediate Suspension of Registration is set forth in the following nonexhaustive summary of facts and law (*see* 21 C.F.R. §§ 1301.36(e) and 1301.37(c), which DEA construes *in pari materia* in this context.)

1. Walgreens' Jupiter Florida Distribution Center is registered with DEA as a distributor in Schedules II-V pursuant to DEA Certificate of Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478. DEA Certificate of Registration RW0277752 expires by its terms on May 31, 2013. The Jupiter Distribution Center is one of 12 Distribution Centers owned and operated by the Walgreen Corporation,

headquartered in Deerfield, Illinois. Walgreens also operates more than 7800 Walgreens retail pharmacies in the United States.

2. Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The drugs most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone; Schedule IV benzodiazepines such as alprazolam, and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these drugs are prescribed in large amounts and in combination with each other as "cocktails" popular with drug seeking individuals. *See East Main Street Pharmacy*, 75 Fed. Reg, 66149, 66153, (2010); *Paul H. Volkman*, 73 FR 30630, 30633-34, 30639 (2008), *pet. for rev. denied*, *Volkman v. DEA*, 567 F.3d 1215 (6th Cir. 2009).

3. Oxycodone is a dangerously addictive Schedule II controlled substance which is known to be highly abused and diverted in the State of Florida. According to the 2010 Florida Medical Examiner's Commission Drug Report, the drug that caused the most deaths in the state of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam.)

4. Since 2009, Walgreens' Jupiter, Florida Distribution Center has been the single largest distributor of oxycodone products in Florida. At about the same time as the abuse of prescription drugs became an epidemic in Florida, Walgreens' Florida retail pharmacies, supplied by Respondent, commanded an increasingly large percentage of the state's growing oxycodone business. In 2010, only 3 Walgreens retail pharmacies were in the top 100 purchasers of oxycodone within Florida. In 2011, 38 Walgreens pharmacies made the top 100 and 6 were in the top 10. Through May 2012, 44 Walgreens pharmacies are in the top 100 oxycodone purchasers, all of them supplied by Respondent.

5. According to DEA records, in 2011, Walgreens operated 7,862 retail pharmacies in the United States. Sixteen of the top 25 largest Walgreens retail oxycodone purchasers, including the top 6 purchasers, were in Florida and supplied by Respondent. The following table shows these 6 stores and their yearly oxycodone purchases for 2009 through 2011:

Store #	Location	Oxycodone Purchases by Dosage Unit 2009	2010	2011
1. 03629	Hudson, FL	388,100	913,900	2,211,700
2. 03099	Ft. Myers, FL	95,800	496,100	2,165,900
3. 06997	Oviedo, FL	80,900	223,500	1,684,900
4. 03836	Port Richey, FL	344,000	849,000	1,406,000
5. 04391	Ft. Pierce, FL	250,000	881,400	1,329,600
6. 04727	Ft. Pierce, FL	153,500	507,100	1,192,000

6. An ongoing DEA investigation of Respondent's distribution practices and policies, combined with both a general examination of dispensing at Walgreens Florida pharmacies as well as a detailed investigation of the dispensing practices at the six pharmacies identified above, demonstrates that Respondent has failed to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels, in violation of 21 U.S.C. §§ 823(b)(1) and (e)(1). Respondent failed to conduct adequate due diligence of its retail stores, including but not limited to, the six stores identified above, and continued to distribute large amounts of controlled substances to pharmacies that it knew or should have known were dispensing those controlled substances pursuant to prescriptions written for other than a legitimate medical purpose by practitioners acting outside the usual course of their professional practice. *See Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007) (revocation based in part on the respondent's recurring distributions of extraordinary quantities of controlled substances to entities that likely diverted the controlled substances by filling unlawful prescriptions, as well as the respondent's failure to conduct due diligence sufficient to protect against the diversion of the controlled substances it distributed).

7. DEA's investigation of Respondent also revealed that Walgreens failed to detect and report suspicious orders by its pharmacy customers, in violation of 21 C.F.R. §1301.74(b). 21 C.F.R. § 1301.74(b) (distributors are required to "design and operate a system to disclose to the registrant suspicious orders of controlled substances . . . suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. at 36,502 (finding that the respondent repeatedly violated federal regulations by failing to report suspicious orders). Walgreens knew or should have known about their obligations to report suspicious orders, as such obligations were spelled out in detail in three letters from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to every registered manufacturer and distributor, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. The purpose and proper implementation of suspicious order reporting programs was further discussed in the industry's own trade association, the

Healthcare Distribution Management Association (HDMA), in "Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances" published in 2008.[1]

8. Notwithstanding the ample guidance available, Walgreens has failed to maintain an adequate suspicious order reporting system and as a result, has ignored readily identifiable orders and ordering patterns that, based on the information available throughout the Walgreens Corporation, should have been obvious signs of diversion occurring at Respondent's customer pharmacies. *See* 21 C.F.R. § 1301.74(b); *see also Southwood Pharm., Inc.*, 72 Fed. Reg. 36,487 (2007).

9. Respondent's practice with regard to suspicious order reporting was to send to the local DEA field office a monthly report labeled "Suspicious Control Drug Orders." Two reports were provided, one for suspicious orders of Schedule II drugs, another for suspicious orders of drugs in Schedules III through V. These reports were transmitted on Respondent's behalf from Walgreens Corporate headquarters in Deerfield, Illinois. Respondent's suspicious order report for December 2011 appears to include suspicious orders placed by its customers for the past 6 months. The report for just suspicious orders of Schedule II drugs is 1712 pages and includes reports on approximately 836 pharmacies in more than a dozen states and Puerto Rico. The reports are based on a formula that assigns an average monthly order for a particular drug, which is then multiplied by a "DEA factor" (which is always 3, regardless of the drug or the average order amount), resulting in a "Trigger" amount, above which orders for the month are reported as suspicious, along with a listing of all orders placed for the particular drug by the reported pharmacy for the month in which the "Trigger" amount was exceeded. This report from the Jupiter Distribution Center covers pharmacies in multiple states and Puerto Rico, yet the average order and trigger amount is the same for a particular drug regardless of the pharmacy's location, the population it serves, or the number of other pharmacies in the area.

10. As made clear in 21 CFR §1301.74(b), *Southwood*, and the December 27, 2007 letter to distributors from the Deputy Assistant Administrator for the Office of Diversion Control, suspicious orders are to be reported *as discovered*, not in a collection of monthly completed transactions. Moreover, commensurate with the obligation to identify and report suspicious orders as they are discovered is the obligation to conduct meaningful due diligence in an investigation of the customer and the particular order to resolve the suspicion and verify that the order is actually being used to fulfill legitimate medical needs. This analysis must take place *before* the order is shipped. No order identified as suspicious should be fulfilled until an assessment of the order's legitimacy is concluded. As such, Respondent's reports, consisting of nothing more than an aggregate of completed transactions, did not comply with the requirement to report suspicious orders as discovered, despite the title Respondent attached to these reports.

[1] See http://www.healthcaredistribution.org/gov_affairs/pdf_controlled/20081113_icg.pdf.

11. A review of the documents Respondent provided as evidence of its "due diligence" on the above listed six pharmacies, demonstrates that Respondent failed to conduct any meaningful investigation or analysis to ensure that the massive amounts of commonly abused, highly addictive controlled substances being ordered by these pharmacies were not being diverted into other than legitimate channels. In response to DEA requests, Respondent has been unable to provide any files related to any effort to adequately verify the legitimacy of any particular order it shipped to its customer stores.

12. Respondent's employee with overall responsibility for Schedule II drug operations (the "CII Function Manager"), raised questions within the corporation about what she correctly identified as unusually large orders for Schedule II narcotics placed regularly by several customer pharmacies. Based on the evidence available to DEA, none of these orders were reported to DEA as suspicious and all appear to have been shipped, without any further due diligence to verify their legitimacy. For example:

    a. In January 2011, Jupiter's CII Function Manager expressed concern about the enormous volume of 30 mg oxycodone being ordered by three stores, Walgreens #'s 7298, 3836, and 5018, concluding in an email to the "Manager, Rx Inventory Drug Stores" at Walgreens' Corporate Headquarters in Deerfield, Illinois, that she felt the stores needed "to justify the large quantity." With regard to store # 3836 in Port Richey, Florida, she noted that Respondent had shipped this store 3271 bottles of 100 count 30 mg oxycodone (i.e., 327,100 dosage units) in the 40 day period from 12/1/10 to 1/10/11, causing her to question *"how they can even house this many bottle[s]."* She then inquired of the same corporate manager: *"How do we go about checking the validity of these orders?"*

    b. Despite having raised these concerns from the distributor to a supervisor at corporate headquarters, none of these orders were reported as suspicious and there appears to have been no other inquiry conducted into the circumstances of the enormous amount of narcotics being shipped to store # 3836 in Port Richey, a town of less than 3000 people in a county with a population of only approximately 475,000. Despite the fact that a distribution center manager had raised questions about this store's ordering volume to a corporate manager in January 2011, the very next month, Respondent filled and shipped orders totaling another 285,800 dosage units of 30 milligram oxycodone to the same pharmacy. Again, there is no evidence of any due diligence conducted by Respondent or anyone else within the corporation to verify the legitimacy of these orders in order to fulfill their obligation to maintain effective controls against diversion.

13. According to documents received from Walgreens Corporate Headquarters, on April 2, 2012, Walgreens revised its suspicious order policy, but made the policy retroactively effective to January 1, 2012. The policy states, in pertinent part, that "Effective calendar year 2012, the Controlled Substance Order Monitoring and Prevention System prevents suspicious control drugs from being shipped to the stores. In calendar year 2012, because of the program mentioned, suspicious control drug reports are no longer generated as their shipment is prevented by the system."

14. This policy ignores the fact that the reporting requirement of 21 CFR § 1301.74(b) applies to *orders*, not shipments. A suspicious order placed by a customer pharmacy is made no less suspicious by application of a system designed to reduce or eliminate such orders prior to shipping. Construing the regulation this way defeats the essential purpose of the suspicious order requirement, which, as I stated in *Southwood*, is "to provide investigators in the field with information regarding potential illegal activity in an expeditious manner." 72 FR at 36501.

15. Respondent's local DEA field office within the Miami Field Division has not received a suspicious order report for any orders placed in 2012, despite the fact that Respondent has received and shipped multiple orders this year that, using the criteria Walgreens employed in 2011, would have exceeded the trigger amount previously used to report these sales.

16. The available evidence suggests that Respondent's abdication of its responsibilities as an individual registrant was at least facilitated by a push from Walgreens Corporate headquarters to increase oxycodone sales at its Florida retail pharmacies, all of which received their Schedule II controlled substances from Respondent. I also note that during the relevant time herein, Walgreens had in effect compensation programs for pharmacy employees in which bonuses were based on the number of prescriptions filled at the pharmacy. This bonus program, combined with a concerted, corporate directed effort to increase oxycodone sales, served as an incentive for pharmacists and pharmacy technicians to ignore the "red flags" of diversion presented by these prescriptions, many of which, in the proper exercise of the pharmacist's corresponding responsibility under 21 CFR §1306.04(a), should have resulted in a refusal to fill.

    a. In July 2010, Walgreens' corporate headquarters conducted an analysis of oxycodone dispensing for the prior month at its Florida retail pharmacies and produced an 11 page spreadsheet, ranking all Florida stores by the number of oxycodone prescriptions dispensed in June. The spreadsheet was sent to Walgreens' market pharmacy supervisors in Florida on July 29, 2010, with the admonition that they "*look at stores on the bottom end .... We need to make sure we aren't turning legitimate scripts away. Please reinforce.*" A corporate market director of pharmacy operations did reinforce this message to Florida market pharmacy supervisors, highlighting that their "*busiest store in Florida*" was filling almost 18 oxycodone prescriptions per day, yet "*We also have stores doing about 1 a day. Are we turning away good customers?*"

    b. At roughly the same time as Walgreens' supervisors were urging its Florida pharmacies to increase their oxycodone sales, Florida enacted new laws to combat the prescription drug abuse problem, particularly the devastating effects of oxycodone and other abused drugs dispensed directly from rogue pain clinics, commonly known as "pill mills." These new laws went into effect on October 1, 2010 and severely restricted the ability of pain clinics and physicians to dispense controlled substances directly from the clinics. The purpose of these legislative changes was to stem the overwhelming tide of controlled substances being

diverted from pill mills and into illicit channels for sale and recreational abuse. As a result, Florida pharmacies and the distributors who served them knew or should have known that starting in late 2010, there would be a significant increase in requests to dispense pursuant to prescriptions issued by physicians associated with the pain clinics.

c. Walgreens store # 06997 in Oviedo, Florida, was ranked 444th on the above-referenced Walgreens' ranking of oxycodone sales generated at its Florida retail pharmacies, filling on average only 4 oxycodone prescriptions per day in June 2010. DEA tracks pharmacy activity not by prescriptions but by dosage units of a particular drug purchased by the pharmacy for retail sales. In 2010, the national average for oxycodone sales to retail pharmacies was 70,395 dosage units per year, or about 5,866 dosage units per month. This store's oxycodone sales began to increase drastically, as shown by the fact that in June 2010, Walgreens store #06997 purchased just 6,600 dosage units of oxycodone products. One year later, in June 2011, this same pharmacy purchased 169,700 dosage units of oxycodone.

d. Oviedo is a town of about 34,000 people and is home to two Walgreens retail pharmacies. Beginning in late 2010, these two pharmacies became the site of multiple arrests by the local police for drug offenses. The local Chief of Police began writing letters to the pharmacies after each arrest stemming from prescriptions they filled. These letters informed the pharmacy of the circumstances of the arrest and that the dispensed drugs were not being used for treatment. They further provided the pharmacy with the name and date of birth not only of the person whose prescription they filled, but also of others associated with the illegal distribution of the dispensed drugs. These letters then concluded with a request for the pharmacy's help in "dealing with the prescription medication epidemic" by soliciting a commitment to stop further incidents.

e. The Oviedo Police Chief's concerns reached the highest levels of Walgreens' Loss Prevention Operations, with the Director of Divisional Loss Prevention noting in an email on January 28, 2011 that "*[e]vidently the Chief of Police is concerned that we are filling too many C2 prescriptions.... From what I've been told, he is referencing 100 plus incidents/arrests in his jurisdiction.*" Walgreens' response was to "*take a look at this market . . . and see if we have an increase in dispensing.*"

f. The Oviedo Police Chief convened a meeting with Walgreens Loss Prevention officials on February 10, 2011, in an effort to further bring awareness of the problems he was seeing at their stores and to brief them on the number of arrests at each location. On March 15, 2011, he sent identical letters to both the Chairman and CEO of Walgreens, asking them for their support and assistance in combating the prescription drug epidemic, informing them that Oviedo "*has seen the parking lots of your stores become a bastion of illegal drug sales and drug use*" where once the prescriptions are filled, "*the drugs are sold, distributed as payment, crushed and snorted, liquefied and injected, or multiple pills swallowed while in the parking lot of your pharmacies.*"

g. Despite being informed at the highest levels of ongoing diversion and drug-related criminal activity directly stemming from dispensing at these pharmacies, and bearing in mind that the average U.S. retail pharmacy in 2011 purchased only 73,000 dosage units of *all formulations* of oxycodone *for the entire year*, the Walgreens corporation, through Respondent, responded to this information about one of its stores by shipping the following quantities of 30 milligram formulation oxycodone to Oviedo store 06997:

(i) February 2011	75,300 dosage units
(ii) March 2011	72,900 dosage units
(iii) April 2011	101,700 dosage units
(iv) May 2011	133,900 dosage units
(v) June 2011	115,200 dosage units
(vi) July 2011	145,300 dosage units

h. Perhaps even more significant than the enormous amount of oxycodone Respondent shipped to this store despite the information provided by the Chief of Police to its pharmacists and most senior leaders, is the fact that the dispensing records for both Oviedo Walgreens pharmacies show that on multiple occasions, they each dispensed additional prescriptions of commonly diverted narcotics to the same individuals who they knew had been previously arrested for drug offenses at their pharmacies. I find this to be a staggering disregard of Walgreens' obligations under the Controlled Substances Act.

17. While the detailed information provided by the Chief of Police put Respondent and its parent company on notice of actual diversion occurring at the two Oviedo pharmacies, Respondent had ample other indications that its pharmacies were direct and significant contributors to the epidemic of prescription drug abuse and diversion in Florida, yet it largely ignored these indicators, at all levels of the corporate structure. An inexhaustive description of some of these indicators are the following:

a. On September 27, 2010, a pharmacist working at Walgreens # 04727 in Ft. Pierce reported to law enforcement that he mistakenly provided an extra 120 dosage units of 15 milligram oxycodone to a customer. When the pharmacist tried to call the customer to request he return the mistakenly dispensed oxycodone, he was told by the customer's girlfriend that the customer was an addict who sells his pills and views the extra oxycodone as a "pot of gold" which he would not return. Despite this incident, Walgreens # 04727 filled several additional oxycodone prescriptions issued to this customer in December 2010 and January 2011.

b. On November 4, 2010, a Walgreens # 04727 pharmacist reported to police that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a twenty-four year old male who she then witnessed transfer the drugs to a female in the store. The female entered the pharmacy restroom, leaving behind evidence indicating she had smoked the oxycodone. Despite this incident, Walgreens # 04727 continued to fill the same customer's oxycodone and alprazolam prescriptions on several occasions in November and December 2010 and January 2011.

c. On December 21, 2010, a pharmacist employed by Walgreens Pharmacy # 3629 in Hudson, Florida reported to the Pasco County (Florida) Sheriff's Office that an individual had attempted to fill a prescription for 270 dosage units of thirty milligram oxycodone, but ran from the pharmacy after learning the pharmacy had contacted law enforcement, suspecting the prescription was a forgery. Despite this incident, the same pharmacy that reported this customer to the Sheriff's Office in December continued to fill the same customer's oxycodone prescriptions in February, March, April, May and October of 2011.

18. On or about March 2011, corporate officials at Walgreens headquarters in Illinois initiated a Florida pharmacy store review initially entitled "Focus on Profit" and later changed to "Focus on Compliance." The purpose of this review was to address the "significant increase in the number of [Schedule II controlled substance] prescriptions we are filling in [Florida]" after the October 2010 change in Florida law regarding pain clinics. The initial pilot survey asked the following questions, amongst others: "Do pain management clinic patients come all at once or in a steady stream?" and "Do you see an increase in pain management prescriptions on the day the warehouse order is received?" On May 17, 2011, in an email with the subject heading "Florida Focus on Profit," a Walgreen Co. corporate attorney reviewed the survey and regarding these two questions, stated "*If these are legitimate indicators of inappropriate prescriptions perhaps we should consider not documenting our own potential noncompliance.*" The surveys that ultimately were used in the Focus on Compliance initiative did not contain those questions. By omitting these questions in order to avoid gathering information pertinent to whether or not pain clinic patients were engaged in diversion, the Walgreens Corporation and Respondent as a corporate subsidiary, ignored its statutory and regulatory obligation to maintain effective controls against the diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. *See* 21 U.S.C. § 823(b) and (e).

19. Apparently as part of this "Focus On Compliance," Walgreens sought to develop and implement "Oxycodone Action Plans" within its districts in Florida in an attempt to reduce the volume of oxycodone dispensing on behalf of pain clinics. For store # 3629 in Hudson, the plan devised by District Pharmacy and Loss Prevention supervisors in a memo dated August 23, 2011 included *"contacting the Jupiter warehouse and designating order limits for Oxycodone."* The plan, effective immediately, was to "limit" the Hudson store to orders of no more than 100 bottles of 100 count 30 milligram oxycodone. Notwithstanding the memo and the plan to limit store #3629's purchases to no more than 100 bottles, Respondent subsequently

shipped the following orders to store 3629:

Date	Bottles	Dosage Units
09/26/11	331	33,100
10/10/11	371	37,100
11/29/11	200	20,000
12/06/11	113	11,300
12/13/11	150	15,000

Respondent's inability to enforce a very simple, modest limitation on this one pharmacy is further evidence of its failure to maintain effective controls against diversion, even in the rare instance when it tried to do so.

20. In mid to late 2011 and continuing into 2012, Walgreens undertook to reduce the volume of oxycodone dispensing at its high-volume pharmacies and in some cases, did, in fact, achieve a relatively significant reduction in Schedule II dispensing at these stores. Additionally, in late May, 2012, approximately seven weeks after Administrative Inspection Warrants were served on six Walgreens retail pharmacies and Respondent, Walgreens suspended dispensing of Schedule II drugs as well as Alprazolam and Carisoprodol at these six pharmacies and two others. In my assessment of the imminent danger posed by Respondent's continued registration, I have considered these remedial measures, as well as Walgreens' claims that it continues to revise its suspicious order reporting system to prevent the excesses that occurred in 2010 and 2011. In my judgment, and in the exercise of the discretion afforded me by 21 U.S.C. § 824(d), the danger posed by Respondent's continued registration is only slightly mitigated by the dispensing restrictions enacted at these eight pharmacies.

21. To reiterate, my concerns with Respondent's distribution practices are not limited to the six Walgreens pharmacies discussed herein. Respondent distributes to over 800 other retail pharmacies in Florida alone, many of which dispense oxycodone in amounts far in excess of the U.S. and Florida averages and which also experienced dramatic increases in their distribution of oxycodone from at least 2009 to the present. No fewer than 43 Walgreens pharmacies in Florida purchased in excess of 500,000 dosage units of oxycodone in 2011, despite a national average of approximately 74,000 dosage units for all U.S. pharmacies and an average of approximately 110,00 dosage units for all Florida Walgreens pharmacies. Florida remains the epicenter of this country's prescription drug abuse problem and notwithstanding the cessation of Schedule II dispensing at eight of its retail customers, Respondent remains the top distributor of the most dangerous prescription drugs in Florida, and still has not made a single suspicious order report in calendar year 2012.

22. Through May of this year, Respondent's customers included 44 Walgreens retail pharmacies on the list of the 100 top oxycodone purchasing pharmacies in Florida.[2] Respondent continues to distribute large amounts of oxycodone while it appears to continue to misunderstand or ignore its obligation to maintain effective controls against diversion by reporting suspicious orders and conducting due diligence on its customer stores to verify the legitimacy of their orders. Thus, the fact that Walgreens stopped selling Schedule II controlled substances to a handful of retail pharmacies – virtually all of which Walgreens also knew were themselves under DEA investigation at the time Walgreens stopped distributing to these pharmacies – does little to mollify my concerns about the danger posed by Respondent's continued operation. The nature and significance of the problems revealed by DEA's investigation indicate that Respondent's anti-diversion measures are inadequate generally; the problems do not appear to be limited to the pharmacies discussed herein. Consequently, I believe that Respondent's continued operation poses an imminent danger to public health and safety.

23. Voluntary dispensing restrictions enacted either in anticipation of, or in reaction to regulatory action, do not indicate to me that Respondent and its parent company have recognized and adequately reformed the systemic shortcomings discussed herein. On the contrary, when a company undertakes to survey its stores for regulatory compliance, then selectively edits that survey for the explicit purpose of avoiding evidence of its own non-compliance, as Walgreens apparently did in May 2011, claims of effective remedial measures have less credibility. I gave significant weight to the fact that Walgreens appears to have deliberately structured certain of its anti-diversion measures to avoid learning about and/or documenting evidence consistent with diversion. At best, I regard this as deliberate indifference on Walgreens' part as to its obligations as a DEA registrant.

24. My confidence in Walgreens' remedial measures is lessened further by the fact that this manipulation of the compliance survey occurred just one month after Walgreens entered into a nationwide Memorandum of Agreement (MOA) with DEA to resolve an Order to Show Cause issued to a San Diego Walgreens pharmacy based on allegations of unlawful dispensing. Walgreens pledged in this MOA to enact a compliance program at all of its retail pharmacies to detect and prevent diversion of controlled substances and to implement and maintain policies and procedures to ensure that prescriptions for controlled substances are only dispensed to authorized individuals pursuant to federal and state law and regulations. Walgreens' effort to enact such a program in Florida appears to have been, in part, intentionally skewed to avoid actually detecting certain evidence of possible diversion. That Walgreens would actively seek to avoid documenting evidence of possible diversion in its "Focus on Compliance" in Florida immediately after entering this MOA, further contributes to my preliminary finding that Respondent's continued registration during

[2] By way of comparison, only two other national or regional chain pharmacies have stores on this list, one of which has four stores in the top 100, while the other has three.

the pendency of this proceeding constitutes an imminent danger to the public health and safety.

IN view of the foregoing, and based on information before the Agency as of the issuance of this notice, it is my preliminary finding pursuant to 21 U.S.C. §§ 823(f) and 824(a)(4), that Walgreens' continued registration is inconsistent with the public interest. Under the summarized facts and circumstances described herein, it is also my preliminary finding, significantly in light of the rampant and deadly problem of prescription controlled substance abuse in Florida, that Respondent's continued registration while these proceedings are pending constitutes an imminent danger to the public health and safety. *See* 21 U.S.C. § 824(d). Accordingly, pursuant to the provisions of 21 U.S.C. § 824(d) and 21 C.F.R. § 1301.36(e), and the authority granted me under 28 C.F.R. § 0.100, DEA Certificate of Registration RW0277752 is hereby suspended, effective immediately. Such suspension shall remain in effect until a final determination is reached in these proceedings.[3]

PURSUANT to 21 U.S.C. § 824(f) and 21 C.F.R. § 1301.36(f), the Special Agents and Diversion Investigators of the DEA who serve this Order to Show Cause and Immediate Suspension of Registration are authorized to place under seal or to remove for safekeeping all controlled substances that Walgreens possesses pursuant to the registration which I have herein suspended. The said Agents and Investigators are also directed to take into their possession Walgreens's DEA Certificate of Registration RW0277752 and any unused order forms.

THE following procedures are available to you in this matter:

1. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a written request for a hearing in the form set forth in 21 C.F.R. § 1316.47. *See* 21 C.F.R. § 1301.43(a). If Walgreens fails to file such a request, the hearing shall be cancelled in accordance with paragraph 3, below.

2. Within 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, Walgreens may file with the DEA a waiver of hearing together with a written statement regarding its respective positions on the matters of fact and law involved. *See* 21 C.F.R. § 1301.43(c).

3. Should Walgreens decline to file a request for a hearing or, should Walgreens request a hearing and then fail to appear at the designated hearing, Walgreens shall be deemed to have waived the right to a hearing and the DEA may cancel

[3] I have primarily addressed Schedule II controlled substances based on Walgreens' representations that Respondent no longer distributes controlled substances other than Schedule II. This should not be construed as an indication that DEA has concluded that Respondent's distribution practices relating to non-schedule II controlled substances conform to all applicable requirements and obligations. To the contrary, many of the problematic distribution practices noted herein would raise imminent danger concerns with respect to non-Schedule II controlled substances if Respondent were to continue to distribute them.

such hearing, and I may enter my final order in this matter without a hearing based upon the evidence presented to me. *See* 21 C.F.R. §§ 1301.43(d) and 1301.43(e).

Correspondence concerning this matter, including requests referenced in paragraphs 1 and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152. Matters are deemed filed upon receipt by the Hearing Clerk. *See* 21 C.F.R. § 1316.45. A copy of the same shall also be served on the Government counsel listed below and be addressed to the Office of Chief Counsel, Diversion and Regulatory Litigation, 8701 Morrissette Drive, Springfield, VA 22152.

Michele M. Leonhart
Administrator
Drug Enforcement Administration

cc: Hearing Clerk, Office of Administrative Law Judges
Scott Lawson, Counsel for the Government
Jonathan Novak, Counsel for the Government

REQUEST FOR HEARING

Any person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format:

[DATE]

DEA Headquarters
Office of the Administrative Law Judges
Hearing Clerk
8701 Morrissette Drive
Springfield, Virginia 22152

Dear Madam:

The undersigned, [Name of person], hereby requests a hearing in the matter of [Identification of the proceeding].

(A) [State with particularity the interest of the person in the proceeding.]

(B) [State with particularity of the objections or issues, if any concerning which the person desires to be heard.]

(C) [State briefly the position of the person with regard to the particular objections or issues.]

(D) [Name (either registrant, applicant, or attorney), address (including street address, city, state, and zip code), and telephone number (including area code) of person to whom all subsequent notices or mailings in this proceeding should be sent.]

Respectfully yours,

[Signature of registrant, applicant or attorney]

Note: Pursuant to 21 CFR 1316.47(b), the Administrative Law Judge, upon request and showing of good cause, may grant a reasonable extension of time allowing for response to an Order to Show Cause.

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF WALGREEN, CO.	DOCKET NO. 13-01 ADMINISTRATIVE LAW JUDGE JOHN J. MULROONEY, II

GOVERNMENT'S PREHEARING STATEMENT

Scott Lawson
Jonathan Novak
Attorneys
Diversion & Regulatory Litigation
Office of Chief Counsel
8701 Morrissette Drive
Springfield, VA 22152
Tel: 202.307.8038
Fax: 202.307.4946

Date: October 31, 2012

Pursuant to the October 15, 2012 Order for Prehearing Statements, as modified by the October 18, 2012 Order Granting the Respondent's Motion For a Continuance and Amending the Order for Prehearing Statements, the United States Department of Justice, Drug Enforcement Administration (DEA or Government), hereby submits its Prehearing Statement.[1]

I. ISSUE

Whether DEA should revoke DEA Certificate of Registration RW0277752 issued to Walgreen Co. ("Respondent"), pursuant to 21 U.S.C. §§ 824(a)(4) and 823(b) and (e) and deny any pending applications for renewal or modification of such registration, pursuant to 21 U.S.C. § 823(b) and (e).

II. REQUESTED RELIEF

The Government requests revocation of Respondent's DEA Certificate of Registration RW0277752.

III. PROPOSED STIPULATIONS OF FACT[2]

1. Respondent is registered with DEA as a distributor in Schedules II-V under DEA Registration RW0277752 at 15998 Walgreens Drive, Jupiter, Florida 33478.

2. DEA Registration Number RW0277752 expires by its terms on May 31, 2013.

IV. PROPOSED WITNESSES[3]

1. Joseph Rannazzisi
   Deputy Assistant Administrator for Diversion Control
   DEA Headquarters
   8701 Morrissette Drive

[1] The Government is filing separately a Motion For an Extension of Time to file this Prehearing Statement, which was originally due on October 29, 2012. The Government was unable to file by this date due to Hurricane Sandy and the resulting closure of the federal government on October 29 and 30, 2012.

[2] The Government anticipates discussing additional stipulations with Respondent.

[3] At this time the Government has not noticed an expert witness. The Government requests the opportunity to supplement its intended witnesses and testimony if it determines that such an expert is necessary in the presentation of its case, and particularly, if Respondent intends to utilize an expert witness.

Springfield, Virginia 22152

2. Susan Langston
   Diversion Program Manager
   DEA Miami Field Division
   2100 North Commerce Parkway
   Weston, Florida 33326

3. Kyle Wright
   Chief, Targeting and Analysis Unit
   DEA Headquarters
   8701 Morrissette Drive
   Springfield, Virginia 22152

4. Donna Richards
   Acting Diversion Group Supervisor
   DEA Miami Field Division
   2100 North Commerce Parkway
   Weston, Florida 33326

5. Phyllis Garrett
   Diversion Investigator
   DEA Miami Field Division
   2100 North Commerce Parkway
   Weston, Florida 33326

6. Chief Jeffrey Chudnow
   Oviedo Police Department
   300 Alexandria Boulevard
   Oviedo, Florida 32766

7. Robert Varno
   Walgreen Co.
   15998 Walgreens Drive
   Jupiter, Florida 33478

8. Christine Atwell
   Walgreen Co.
   15998 Walgreens Drive
   Jupiter, Florida 33478

9. Kathy L. Federico
   Diversion Group Supervisor
   Milwaukee District Office
   4725 West Electric Avenue
   West Milwaukee, Wisconsin 53219

10. George Corripio
Pharmacist
Walgreen Co. Store # 5079
2423 Orange Ave.
Ft. Pierce, Florida

11. Edward J. Lanzetti
Walgreen Co. Market Loss Prevention Director
7003 Presidents Dr., #250
Orlando, Florida 32809

V. SUMMARY OF TESTIMONY

1. Deputy Assistant Administrator Joseph Rannazzisi

Deputy Assistant Administrator Rannazzisi will describe his background, education and training as a DEA Deputy Assistant Administrator, a law enforcement officer, and a licensed pharmacist. He will further testify substantially as follows:

Prescription drug abuse occurs in the United States at an alarming rate. The 2010 National Survey on Drug Use and Health reveals that approximately 7 million Americans abuse controlled substance pharmaceuticals for non-medical purposes. Second only to marijuana, controlled substance prescription drugs are abused by more people than cocaine, heroin, hallucinogens and inhalants combined. Of all prescription drugs, narcotic pain relievers such as oxycodone, hydrocodone, and oxymorphone are abused most frequently. Each year, roughly 5.1 million people abuse narcotic pain relievers in the United States.

Beginning in late 2008 and continuing to the present, there has been a significant rise in the number of rogue pain clinics whose complicit doctors were initially permitted to dispense millions of dosage units of oxycodone and other abused drugs directly from the clinics. Florida is the epicenter for these illegal pain clinics. DEA, State and local law enforcement investigations reveal that thousands of drug seekers flock to these Florida-based pain clinics to obtain their supply of oxycodone, and other controlled substances such as alprazolam, which is

in turn illegally redistributed in states along the entire east coast and Midwest.

The illicit pain clinics, the pharmacies that fill their scripts, and the wholesale distributors who supply pharmacies without appropriate due diligence (including Respondent), have caused, and continue to cause, millions of dosage units of oxycodone and other controlled substances to be diverted, posing a serious threat to the public health and safety. According to the Florida Medical Examiner's Office, they have seen a 345.9% increase in the number of overdose deaths associated with oxycodone between 2005 and 2010. For 2010, their data showed that approximately 4,091 persons died in Florida alone from an overdose caused by just five drugs: methadone, oxycodone, hydrocodone, benzodiazepines, or morphine.

Furthermore, the abuse of prescription drugs is not isolated to just one drug. Abusers and addicts routinely abuse prescription drugs in combination with one another to enhance the effects. This activity significantly increases the risk of potential harm to the individual. This combination is often referred to as a "cocktail" of hydrocodone or oxycodone used in combination with alprazolam (a benzodiazepine) and carisoprodol. According to the Florida Medical Examiner's Office, they have seen a 127% increase in the number of deaths associated with benzodiazepines in the State of Florida between 2005 and 2010.

On July 1, 2011, the State Health Officer and Surgeon General, Dr. Frank Farmer issued a statewide public health emergency declaration in response to the ongoing problem of prescription drug abuse and diversion in Florida. The press release accompanying this emergency declaration noted more oxycodone is dispensed in the state of Florida than in all remaining states combined. It further stated that in 2010, "98 of the top 100 doctors dispensing Oxycodone nationally were in Florida"; and that "126 million oxycodone pills were dispensed through the top 100 dispensing pharmacies in Florida".

Following changes in Florida law aimed at curbing the problematic dispensing direct from the pain clinics, drug abusers have found other ways to obtain oxycodone and other "cocktail" drugs. Rather than dispensing the drugs directly to "patients," pain clinics and complicit doctors are now forced to write prescriptions for oxycodone and other abused drugs. Drug abusers wanting their prescriptions filled must take their prescriptions to a retail pharmacy. The result was that law enforcement saw immediate and significant increases in the volume of oxycodone dispensed from retail pharmacies across the state of Florida. Retail pharmacies are generally supplied by a DEA-registered wholesale distributor. The doctors and clinics that prescribe oxycodone inappropriately, the pharmacies that dispense their prescriptions, and the wholesale distributors who supply them have caused, and continue to cause, millions of dosage units of oxycodone to be diverted for unlawful use thereby creating an imminent threat to the public health and safety.

Deputy Assistant Administrator Rannazzisi will authenticate and describe the purpose behind three letters sent by DEA to all distributors and manufacturers, including Respondent, on September 27, 2006, February 7, 2007, and December 27, 2007. These letters explained to distributor registrants their obligations to maintain effective controls against diversion and report suspicious orders as part of their duties within the closed system established by the Controlled Substances Act (CSA). He will describe the purpose of the suspicious order requirement of 21 C.F.R. §1301.74(b) and its relationship to the statutory obligation of all distributors to maintain effective controls against diversion of controlled substances pursuant to 21 U.S.C. §§ 823(b)(1) & 823(d)(1). Consistent with the guidance of these letters, he will describe a distributor's obligation to devise and implement an effective system to identify suspicious orders and the obligation to report suspicious orders to DEA as they are discovered. He will further testify that

a distributor has an obligation under the statutory and regulatory scheme to determine the legitimacy of any order it identifies as suspicious prior to fulfilling that order.

He will further testify that distributors have a statutory obligation to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific and industrial channels and that the exercise of this obligation requires a distributor to confirm the legitimacy of all orders prior to filling. He will describe the general ways in which distributors commonly perform and document this due diligence and will describe common indicators of diversion that all distributors should be alert to at their customer pharmacies. He will testify that these obligations apply equally to distributor registrants regardless of whether their customers are independent or chain pharmacies and regardless of whether the distributor and its customers are under common ownership.

Based on the evidence of its' suspicious order program provided by Respondent, he will testify that the Walgreen Co.'s suspicious order program fails to comply with Respondent's obligations under 21 C.F.R. §1301.74(b). He will testify that the "Suspicious Control Drug Orders" report provided to DEA on Respondent's behalf monthly by Walgreen Co. corporate headquarters constitutes nothing more than a monthly report of completed transactions and therefore does not meet the regulatory requirement to report suspicious orders as discovered, as is spelled out in his December 27, 2007 letter to Respondent. In other words, despite the title attached to these compilations of completed transactions, he will testify that they are not suspicious order reports under the regulation. Furthermore, he will testify that based on the documents provided by Walgreen Co., Respondent appears to have conducted little to no investigation or analysis of the orders it reported as suspicious prior to completing the sale of these orders, despite the fact that on a single day, many of these orders greatly exceeded the

monthly threshold established by Respondent for reporting orders of a particular controlled substance as suspicious.

Moreover, he will testify that the monthly reports of completed "suspicious" transactions reported by Respondent were misleading in that they did not report each order received and shipped by Respondent, but instead aggregated the orders shipped on any given day. Further, he will testify that the reports made by Respondent are flawed in that they include all orders for a particular controlled substance shipped to a particular pharmacy in a given month and do not indicate which of these orders are being reported as suspicious. He will testify that based on the foregoing, Respondent did not make a single proper suspicious order report, despite a history of supplying its customers, particularly but not limited to its Florida retail pharmacies, incredibly large amounts of the most commonly abused and diverted controlled substances.

He will testify regarding the Walgreen Co.'s current suspicious order policy, applicable to all of its distribution centers, including Respondent, which indicates that as of January 1, 2012, the company will no longer make suspicious order reports as a result of a system that supposedly prevents shipment of any suspicious orders. He will testify that such a policy evidences a misunderstanding of the suspicious order reporting requirement, which is triggered by suspicious orders for controlled substances, not only when such an order is actually shipped. He will testify that this operating statement on behalf of Respondent is further evidence of the lack of an appropriate system under 21 C.F.R. § 1301.74(b) and is indicative of ineffective controls against the diversion of controlled substances.

Finally, he will discuss the additional requirements imposed upon the Walgreen Co's operation of its retail pharmacies by the Memorandum of Agreement entered into between DEA and Walgreen Co. in April, 2011.

2. Susan Langston, Diversion Program Manager ("DPM"), Miami Field Division (MFD)

DPM Langston will testify to her background, education and training as a DEA Diversion Investigator, Diversion Group Supervisor, and Diversion Program Manager. She will testify substantially as follows:

Since at least 2009, the State of Florida has been the epicenter of a notorious, well-documented epidemic of prescription drug abuse. In July 2011, the Florida Surgeon General declared a Public Health Emergency based on the prescription pill epidemic which results in an average of seven overdose deaths per day in Florida. The controlled substances most commonly associated with this epidemic are typically prescribed at unscrupulous pain clinics by physicians acting outside the usual course of professional practice and include Schedule II pain relievers, such as oxycodone (which is highly addictive and known to be highly abused an diverted in the State of Florida); Schedule IV benzodiazepines, such as alprazolam; and Schedule IV muscle relaxers, such as carisoprodol. Frequently, these controlled substances are prescribed in large amounts and in combination with each other as "cocktails" popular with drug seeking individuals. According to the 2010 Florida Medical Examiner's Commission Drug Report, the drug that caused the most deaths in the State of Florida for 2010 was oxycodone (1,516 deaths), followed by benzodiazepines (1,304 deaths of which 981 were caused by alprazolam). DPM Langston will testify regarding changes to Florida law aimed at curbing this problem that restricted the ability of practitioners to dispense controlled substances to patients and how the epidemic of controlled substance drug abuse and diversion has now shifted to pharmacies.

DPM Langston will explain why Respondent and 6 of its retail pharmacy customers were targeted for investigation. She will testify about statistical information compiled by DEA's

ARCOS ("Automation of Reports and Consolidated Orders System") unit, identifying the largest distributors of oxycodone and related controlled substances in Florida, as well as the largest retail pharmacy purchasers of these substances in Florida from 2008 to the present. She will introduce charts showing these pharmacies' oxycodone purchases from at least 2008 to the present and describe why the size and frequency of these purchases should have created suspicion within Walgreen Co. and Respondent that these pharmacies were diverting controlled substances.

She will testify that on August 19, 2011, DEA met with Walgreens personnel at the DEA MFD offices in Weston, Florida to apprise them of relevant ARCOS information about Walgreens' sales of oxycodone in Florida. Present from Walgreens were Dwayne Pinon (corporate in-house counsel), Ed Forbes (Market Loss Prevention Director), Wesley Rohn (Pharmacy District Supervisor), Joan Bustelo (Pharmacy District Supervisor), Anne-Marie Aldrich (Pharmacy District Supervisor), Cesar Cedeno (Pharmacy District Supervisor), Georgia Lehoczky (Market Pharmacy Director), Robert Espinosa (Pharmacy Supervisor), Lakeisha Axem (Pharmacy Supervisor), Sandra Vazquez (Pharmacy Supervisor) and Susan Thompson, Loss Prevention Manager. She will testify that the Walgreens officials at this meeting were told, amongst other things, that 20 Florida Walgreens pharmacies were in the top 300 of oxycodone purchasers in the United States for the first half of 2011 and within the State of Florida over the same time frame, 100 of the top 300 pharmacy oxycodone purchasers were Walgreens retail pharmacies. Moreover, Florida Walgreens pharmacies purchased more than double the average amount of oxycodone purchased by Florida pharmacies.

DPM Langston will discuss the "Suspicious Control Drug Order" reports received by DEA from Walgreens. She will testify that these reports were sent to DEA from Walgreens Loss

Prevention officials at corporate headquarters in Illinois on behalf of the Jupiter Distribution Center. She will discuss the contents of these reports, how frequently they were submitted, and what DEA was able to glean from an examination of these reports. DPM Langston will testify that the reports were not in compliance with DEA's clear edict regarding what should and should not be contained in a suspicious order report. She will also testify that in 2012, DEA has not received a single suspicious order report from either Walgreens Corporate Headquarters or from the Jupiter distribution center.

DPM Langston will discuss the execution of Administrative Inspection Warrants (AIW), on April 4, 2012 at six Walgreens pharmacies and Respondent, along with the service of an administrative subpoena for additional records from Respondent, the six pharmacies, and their corporate headquarters. She will testify regarding the meaning of the subpoena's request for "due diligence" files and her efforts to communicate this concept to Respondent. Further, she will testify to the types of information traditionally found within such files maintained by distributor registrants and the traditional steps distributors undertake to monitor their customers and assess whether or not they are involved in diversion.

She will also introduce emails produced by Walgreens in response to the subpoena, in which the corporation urges its Florida pharmacy supervisors to increase their oxycodone sales and she will discuss other emails indicating that Walgreens' officials were aware of excessive dispensing at some of these 6 pharmacies, all of whom received their Schedule II controlled substances from Respondent. She will discuss Walgreen Co.'s dispensing guidelines for its Florida pharmacies and the development and results of a survey entitled "Focus on Compliance", the purpose of which was to assess the scope of the diversion problem at Walgreen's Florida pharmacies.

DPM Langston will testify about multiple specific suspicious orders placed by the six related Walgreens pharmacies during 2011, which were filled despite their suspicious nature and without Respondent conducting any due diligence to ensure these orders were not being diverted. DPM Langston will discuss the specific order dates, the objective suspicious factors related to the orders, such as size and quantity, as well as the subjective factors creating a situation in which Walgreens knew or should have known that the orders were suspicious and that these pharmacies' dispensing practices posed an unreasonable risk of diversion. DPM Langston will discuss due diligence steps that could have and should have been taken before the distribution center shipped the orders. She will also describe numerous "red flags" of diversion evident from a review of the records available to Respondent from the individual pharmacies it served.

3. Office of Diversion Control, Unit Chief Kyle Wright

Mr. Wright will testify to his background, education and training as the Targeting and Analysis Unit Chief in the Office of Diversion Control. He will further testify as follows:

Mr. Wright will testify regarding the Automation of Reports and Consolidated Orders System ("ARCOS") data regarding Respondent's sales of controlled substances. He will testify to the background of ARCOS, its purpose, the information ARCOS contains, and how the information is used by DEA to identify potential diversion of controlled substances. He will testify that he used ARCOS information to conduct an analysis of Respondent's sales of controlled substances. Specifically, he will testify with respect to the ARCOS information for Respondent's top six retail pharmacy customers. Wright will further authenticate charts showing comparative levels of controlled substance purchases among Respondent's various retail chain customers from 2008 to the present, to include the average oxycodone purchasing by all of Respondent's customers; its Florida customers; and the six targeted Walgreens pharmacies.

Wright will further testify to the importance of accurate and complete reporting to ARCOS and will testify that a distributor who reports in a manner that consolidates multiple orders under separate DEA Forms 222 into a single Form 222 is not making a complete and accurate report. Wright will authenticate documents showing Respondent's ARCOS reporting on a number of occasions and compare this reporting to the actual sales information from the source documents.

4. Acting Group Supervisor ("A/GS") Donna Richards

A/GS Donna Richards will testify to her background, education and training as a DEA Diversion Investigator and Group Supervisor. She will testify substantially as follows:

A/GS Richards conducted a thorough review of the materials provided by Walgreens in response to the administrative subpoena issued by DEA. She will testify that her review of these documents produced no actual showing of any due diligence exercised by Respondent to verify the legitimacy of their increasingly frequent and large orders for highly abused controlled substances. The one exception A/GS Richards will note are several emails from the Jupiter distribution center CII Function Manager, Christine Atwell, questioning the size and frequency of orders from particular pharmacies. Richards will testify that despite Respondent's apparent concern about the orders it was fulfilling on behalf of these pharmacies, Respondent continued to ship suspiciously large quantities of controlled substances to these pharmacies and did not properly report any of the orders that Atwell questioned, or that were subsequently shipped to these pharmacies as suspicious. Richards will testify that based on the Walgreen Co.'s response to DEA's request for due diligence files, Respondent filled these orders without adequately resolving Atwell's concerns or otherwise conducting any investigation of these orders to determine that they were not being diverted.

Richards will further testify about several particular incidents occurring at Respondent's customer pharmacies that should have increased Respondent's scrutiny of these customers, all of whom were already purchasing unusually large quantities of the most commonly abused and diverted controlled substances. One of these incidents occurred in December 2010, at Walgreens store 03629 in Hudson, Florida. An individual attempted to fill a prescription for 270 thirty milligram oxycodone tablets but abruptly left the pharmacy without the narcotics he was seeking after apparently learning that pharmacy personnel, who had reviewed the prescription and suspected it was a forgery, had contacted law enforcement. Despite being put on notice that this customer was likely diverting, Walgreens 03629 continued filling prescriptions for the customer through October 2011. All of the prescriptions were for oxycodone, hydromorphone and/or alprazolam, were paid for in cash and issued by physicians located a significant distance from Walgreens 03629. She will further testify that efforts by Walgreens to impose order limits on this particular store in light of its problematic dispensing did not succeed.

Similarly, Richards will testify that on September 27, 2010, a pharmacist at Walgreens store 04727 in Ft. Pierce, Florida, reported to local law enforcement that he mistakenly provided an extra 120 dosage units of oxycodone 15mg to a customer. The pharmacist stated that when he spoke to the customer's girlfriend to request the return of the oxycodone, the girlfriend said that the customer was an addict who sold his pills and viewed the extra prescription as a "pot of gold." Despite this incident, Walgreens 04727 continued to fill this customer's prescriptions for oxycodone 15mg and oxycodone 30mg on December 30, 2010 and January 26, 2011.

On November 4, 2010, a Walgreens 04727 pharmacist reported to local law enforcement that she dispensed a prescription for 60 dosage units of oxycodone 15mg to a customer. The pharmacist witnessed the customer hand the prescription to a female in the store. The female

entered the restroom with the prescription and upon leaving the restroom, left evidence (aluminum foil with burn marks and pill residue) indicating that she had used the oxycodone in an illicit manner. Despite this incident, Walgreens 04727 continued to fill the customer's oxycodone and alprazolam prescriptions on November 30, 2010, December 13, 2010, December 27, 2010, and January 24, 2011. Additionally, on two of these occasions, the pharmacist noted on the prescription that the customer did not have identification and/or a passport.

On October 28, 2011, the Sheriff of St. Lucie County notified Walgreens 04727 by letter that it needed to take action to stem the tide of prescription drug diversion. St. Lucie County Sheriff Ken Mascara requested Walgreens 04727's "help in dealing the with prescription painkiller epidemic" in St. Lucie County and Florida by "closely scrutinizing" prescriptions for Schedule II narcotics, written by out-of-town physicians and/or written for out-of town individuals. Nevertheless, Walgreens 04727 continued its practice of filling numerous opiate/opioid prescriptions issued by out-of-town physicians through early 2012. Several of these out-of town physicians subsequently surrendered their registrations for cause and/or were subject to state action for their conduct involving controlled substances prescriptions.

She will also provide additional examples of orders for controlled substances received by Respondent that, given the information available to the Walgreen Co., including the above-related police incidents and the below-summarized testimony of Oviedo Police Chief Chudnow, should have been considered suspicious. She will provide testimony that despite clear "red flags" of diversion at some of its customer pharmacies, the distribution center shipped suspicious orders to these pharmacies without executing any due diligence to resolve the potential for diversion.

5. Diversion Investigator ("DI") Phyllis Garrett

DI Phyllis Garrett will testify to her background, education and training as a DEA Diversion Investigator. She will testify as follows:

A review of the ARCOS information reported by the Jupiter distribution center to DEA revealed failures to report complete and accurate information to ARCOS. Specifically, DI Garrett will point to examples where Walgreens reported a single ordered quantity of Schedule II controlled substances, while the actual amounts were ordered over several DEA 222 forms, amounting to several separate transactions instead of one. DI Garrett's testimony, along with that of Kyle Wright, will be used to admit documents showing these failures to report completely and accurately.

She will introduce evidence of particular shipments of 30mg oxycodone to the six pharmacies named in the Order to Show Cause and will describe the characteristics of these orders that should have triggered both a suspicious order report and additional investigation from Respondent prior to shipping.

6. Oviedo Chief of Police Jeffrey Chudnow

Chief Chudnow will testify about his background, training and experience as a police officer and as the Chief of Police for Oveido, Florida. Chief Chudnow will testify about the very tangible effects that the diversion of controlled substances has had on the city of Oveido, as evidenced by increases in, among other things, crime rates and overdoses. Chief Chudnow will testify about his department's knowledge of Walgreens 06997, as well as another Walgreens within the city limits, as centers for illicit controlled substance sales and use.

The Oveido Police Department (OPD) made numerous arrests for illegal distribution of

controlled substances in 2010 and 2011 related to controlled substances dispensed at the two Walgreens pharmacies, with many of the illicit transactions preceding these arrests occurring in the parking lots of the stores. Chief Chudnow will testify that it was his practice following one of these arrests to send a letter to the pharmacy which dispensed the controlled substance being diverted, notifying them of the details and asking for the pharmacy's assistance in preventing future diversion. Chief Chudnow sent dozens of these letters, at least five of which will be offered into evidence because, as noted in the ISO, Walgreens Store 06997 continued to dispense to some of these individuals even after being notified of their arrest.[4]

On February 10, 2011, Chief Chudnow met with Ed Lanzetti, Walgreens Market Loss Prevention Director, and another Walgreens official. At the meeting, Chief Chudnow presented Mr. Lanzetti with numerous statistics and facts regarding controlled substance arrests related to Walgreens' two Oveido pharmacies. These statistics included numbers and types of drug-related arrests, types of controlled substances seized per arrest, and statistics showing the names of doctors whose prescriptions were related to diversion arrests. Despite being given this information, Walgreens 06997 continued to fill prescriptions for these associated doctors subsequent to the February meeting with Chief Chudnow.

On March 15, 2011, Chief Chudnow sent letters to Alan G. McNally, Chairman of Walgreens Corporation and to Gregory D. Wasson, President and CEO of Walgreens Corporation, informing them about the numerous controlled substance arrests taking place at the Oveido Walgreens pharmacies and the effects on the community of Oveido, and asking for their assistance in stopping these problems. Chief Chudnow never received any response to his request for assistance from anyone at Walgreens Corporation.

[4] DEA will offer the evidence of subsequent dispensing to the subjects of Chudnow's letters through a Diversion Investigator and will specify these individuals and supporting documents in a Supplemental Prehearing Statement, after moving for a protective order concerning the personal information to be disclosed in these exhibits.

7. Robert Varno

Varno will be asked to testify about his experience as Respondent's Distribution Center Manager in Jupiter, Florida from June 2001 until June 2012. Varno will testify about his responsibilities as the manager of the distribution center, including the filling of orders for all of the Walgreens retail pharmacies serviced by the Jupiter distribution center. Varno will be asked to explain the distribution of controlled substances to the Walgreens retail pharmacies, including the use of DEA Form 222 for filling orders for Schedule II controlled substances. Varno will testify regarding his knowledge and use of shipping information reported to ARCOS, as well as Suspicious Order Reports, his understanding of their creation and his use of these reports in managing the distribution center. He will discuss how these reports were received and stored at the distribution center, his utilization of these reports, and how these reports impacted shipping operations at the distribution center. Varno will testify about his training in anti-diversion measures by Walgreen's Headquarters and/or Loss Prevention officials, particularly those portions of his training focusing on Florida's well-known epidemic of prescription drug abuse. He will also testify about his own knowledge of the prescription drug problem in Florida and how that awareness impacted operations at Respondent, particularly with regard to identifying and verifying suspicious orders of commonly abused painkillers.

8. Christine Atwell

Christine Atwell will be asked to testify about her more than six years of experience as the CII Function Manager at the Walgreens distribution center in Jupiter, Florida. Atwell will explain the role of the CII Function Manager as part of the distribution center operations, including her functions while serving in that role. She will explain the system for filling orders for Schedule II controlled substances in place in 2010 and 2011, including the filling of standard

orders, the filling of "PDQ[5]" orders and the filling of orders for a quantity beyond the stock on hand at the distribution center. Atwell will discuss how the Distribution Center handled orders placed directly by pharmacy employees in addition to the automated system. She will testify about the process of reviewing orders for controlled substances received at the distribution center, as well as about the guidance and training she received from Walgreen Co. on how to evaluate special orders. Atwell is expected to testify that she had full approval authority on all special orders placed by pharmacies. She will testify about how the automated system handled DEA Form 222 documentation of orders filled by the distribution center, as well as any controlled substances ordered but not filled by the distribution center.

Atwell will testify regarding her knowledge and use of information reported to ARCOS, as well as Suspicious Order Reports, to include her understanding of their creation and her use of these reports in managing the distribution center's CII functions. She will testify about her training in anti-diversion measures by Walgreen's Headquarters and/or Loss Prevention officials, particularly those portions of this training focusing on Florida's well-known epidemic of prescription drug abuse. She will also testify about her own knowledge of the prescription drug problem in Florida and how that awareness impacted operations at Respondent, particularly with regard to identifying and verifying suspicious orders of commonly abused painkillers.

As the CII Function Manager, Atwell will testify regarding emails she sent to Walgreens corporate personnel, including Barbara Martin and Distribution Center Manager Rob Varno, voicing concerns about the unusual size and frequency of orders being placed by several pharmacies. She will testify about Walgreens response to those concerns and her awareness of any efforts by Walgreens to address the prescription drug problem both nationally and within

[5] PDQ is internal vernacular used by Walgreens for "Pretty Darn Quick," or for orders received daily at the distribution center for fast turnaround outside the regular weekly orders.

Florida.

Atwell will discuss changes to the automated filling systems implemented at the Jupiter Distribution Center in 2012. She will also discuss her understanding of the suspicious order reports produced by Walgreens, including that she has no input into the creation of these reports and she never utilized these reports as part of her role as CII Function Manager at the distribution center. She will testify that during her tenure as the CII Function Manager at the Jupiter distribution center, she has never stopped an order from being filled and distributed. [6]

9. Group Supervisor ("GS") Kathy Federico

GS Federico will testify to her background, education and training as a DEA Group Supervisor. She will testify as follows:

On June 14, 2012, GS Federico, of the DEA Milwaukee District Office, spoke with Dwayne Pinon, in-house corporate counsel for Walgreen, Co., in a telephone interview. During the interview, Pinon stated that Walgreens' prior suspicious order reporting system was based on a formula for Pseudoephedrine reporting in the DEA Chemical Handlers Handbook. Pinon stated that the old system automatically reported any orders for quantities above the algorithm's threshold limit. He stated that DEA had informed Walgreens that this algorithm reporting system was outdated and that Walgreens needed to establish their own system for reporting suspicious orders. Pinon stated that the old reports were not suspicious orders, but were in fact just orders that "bounced off" the old reporting system. Pinon informed Federico that Walgreens had implemented a new system which they hoped to present to DEA at some point. The new system set limits on a pharmacy ordering controlled substances based on their sales history, and

[6] Both Ms. Atwell and Mr. Varno were interviewed by DEA in August, 2012, with counsel for Respondent present. The Government reserves the right to present evidence of their statements through the testimony of DI's Richards and/or Garrett, particularly if either or both do not testify at the hearing.

any order over the set limit would trigger an alert to Walgreens Loss Prevention. Loss Prevention would then resolve the order. Pinon stated that any orders that Loss Prevention could not resolve would be reported to DEA. However, he stated that initial implementation of this new version of the Suspicious Order Monitoring System had produced "thousands" of allegedly suspicious orders, and was thus still being adjusted to produce different results.

10. George Corripio

George Corripio will testify about his thirty-one (31) years of experience as a pharmacist, and his current position as a Walgreen's Staff Pharmacist at Walgreens #5079 at 2423 Orange Avenue, Ft. Pierce, Florida 34950. Corripio will testify about a brief period in 2011 when he worked at Walgreens #4727, also located in Ft. Pierce, Florida. Corripio will testify as follows:

Unlike the customers at The clientele at Walgreens #4727 was "heavy CII traffic," and that "80% of the clientele was oxy[codone]." In his professional opinion, the diagnoses did not match the customers, as most of the clientele were young people and most of the diagnoses were for back pain. He felt that most of the customers were not telling the truth. The customers were young, they seemed to all now each other, and they often appeared to be under the influence. Often the clientele would present "cocktail prescriptions." On one occasion, a female customer presented a prescription for ten opiates, which is the type of prescription dispensed to a patient suffering from terminal illness.

Corripio will testify about his general discomfort at filling oxycodone prescriptions at Walgreens #4727, and about how supervising pharmacist did not seem bothered by the clientele and offered to fill prescriptions for Corripio that he felt uncomfortable filling. She suggested that as long as the pharmacy had a diagnosis code for the prescription, they were fine to fill. When Corripio refused to fill a prescription, the customer would often ask when the female pharmacist

was coming back.

Corripio will testify that in his professional opinion, any reasonable pharmacist and technician would know that something was not right with the situation going on at the pharmacy. Corripio brought the situation to the attention of the local police department to seek help with the problems. Corripio will further testify that he believed his District pharmacy supervisor knew about the dispensing practices at Store # 4727. [7]

11. Edward J. Lanzetti

Mr.Lanzetti will testify about his employment and duties at Walgreens as a Market Loss Prevention Director. He will be asked to describe his knowledge of the prescription drug abuse problem in Florida and about Walgreens' efforts to combat these issues. He will be asked to describe the Loss Prevention program as it pertains to anti-diversion measures and the methods used by Walgreens' Loss Prevention program to detect and prevent diversion at its pharmacies. Lanzetti will be asked about the increases in oxycodone sales at Walgreens pharmacies in 2010. He will also be questioned about his meeting with Chief Jeffrey Chudnow of the Oviedo Police Department, and about any actions taken in response by the Walgreen Corporation.

VI. PROPOSED DOCUMENTS

Exhibit	Description	Approx. # Pages
1.	DEA Certificate of Registration RW0277752 (attached hereto)	1
2.	Sep 27, 2006 Letter from Deputy Asst. Administrator to Respondent	4
3.	Feb 7, 2007 Letter from Deputy Asst. Administrator to Respondent	2

[7] Mr. Corripio was also interviewed by DEA in August, 2012, with counsel for Respondent present. The Government reserves the right to present evidence his statements through the testimony of DI's Richards and/or Garrett, particularly if Corripio does not testify at the hearing.

Exhibit	Description	Approx. # Pages
4.	Dec 27, 2007 Letter from Deputy Asst. Administrator to Respondent	4
5.	2011 Memorandum of Agreement between DEA and Walgreen Co.	7
6.	Florida Declaration of Public Health Emergency	3
7.	HDMA Guidance on Suspicious Order Reporting	16
8.	Walgreen Policy: Handling Suspicious Drug Orders, Revised 2/15/05	1
9.	Walgreen Policy: Handling Suspicious Orders and Loss of Controlled Drugs, Revised 2/15/05	1
10.	Walgreen: Handwritten Revisions to Suspicious Order Policies, undated	2
11.	Walgreen Policy: Handling Suspicious Drug Orders, Revised 04/02/202 (sic)	1
12.	Walgreen Policy: Handling Suspicious Orders and Loss of Controlled Drugs, Revised 04/02/2012	1
13.	"Controlled Substance Threshold" Project P09002, Feb. 2009	18
14.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Dec. 30, 2011	1500+ *
15.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Nov. 30, 2011	1500+ *
16.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Oct. 31, 2011	1500+ *
17.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated Sep. 30, 2011	1500+ *
18.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated July 31, 2011	1500+ *
19.	Jupiter CII Suspicious Control Drug Orders Report with cover letter dated May 5, 2011	1500+ *
20.	Chart of Top Oxycodone Dispensing Florida Pharmacies, 2008-2012.	5
21.	Chart of Oxycodone Sales to Selected Walgreens Pharmacies, 2006-2012	7
22.	Chart of Oxycodone Average Sales: US average, Florida average, Walgreens Nationwide Average, Walgreens Florida Average.	2
23.	Chart of Oxycodone 30 mg Orders Shipped to Selected Pharmacies	5

Exhibit	Description	Approx. # Pages
24.	2011 MOA between Walgreens and DEA	7
25.	Chart and Supporting Documents – Inaccurate ARCOS Reporting	10
26.	Excerpts from DEA Pharmacist Manual	5
27.	Chart: Oxycodone Sales Comparisons of Selected Walgreens Pharmacies	4
28.	Oviedo Police Department Letters to Walgreens	10
29.	Walgreen Emails Re: Oxycodone Sales **	2
30.	Walgreens Emails re: pharmacy orders **	15
31.	Walgreens Emails re: Ft. Pierce Pharmacies 4727 & 4391 **	8
32.	Walgreens Email about Oviedo Police Chief **	2
33.	Walgreens Emails re: Focus on Compliance **	25
34.	Walgreens Emails re: Oxycodone Action Plans **	8
35.	Walgreens Emails re: Dispensing Guidelines **	10
36.	Selected DEA Forms 222 From Respondent	25
37.	ARCOS Information Submitted by Respondent for the transactions in Exhibit 33.	5
38.	Police Reports re: individual incidents at selected pharmacies	15

* The Government will seek to only use excerpts from these reports in order to limit the size of each exhibit well below the number of pages contained within the original report.

** Respondent has informed the Government that it will be providing a Bates-stamped replica of the material it originally provided in response to a subpoena without any numeration. Once received, the Government will use these materials to specify exactly which documents are being used and provide a more detailed exhibit list in subsequent filings.

VII. OTHER MATTERS

As this and related matters not currently before the Court are part of an ongoing investigation, the Government requests the opportunity to supplement this Prehearing Statement as necessary with additional witnesses and documentary evidence. There may also be a need to supplement or revise in response to ongoing litigation brought by Respondent in both the Eastern District of Virginia and the Court of Appeals for the District of Columbia.

Pursuant to the Court's Amended Order for Prehearing Statements, the Government's position at this time is that paragraph 20 of the OTSC/ISO is the only portion of the charging document that is *solely* relevant to the Administrator's findings of an imminent danger to the public health and safety. While other portions of the OTSC/ISO also support this finding, they are also relevant to the issues to be determined herein, particularly at this stage of the proceeding, where the Government is not yet aware of the particular defenses to be raised by Respondent.

VIII. POSITION REGARDING HEARING SITUS

At this time, the Government does not request a change of location for the hearing, though this position is subject to clarification of the means and method of securing the presentation of testimony by civilian witnesses located more than 500 miles from the site of the hearing. *See* 21 U.S.C. § 876. This concern would be substantially alleviated should Respondent agree to produce in person any current employee requested in this Prehearing Statement or supplements thereto.

IX. BEST ESTIMATE AS TO TIME REQUIRED TO PRESENT CASE

The Government anticipates requiring no more than four (4) days to present its case-in-chief, exclusive of cross-examination and rebuttal.

Respectfully submitted,

SCOTT LAWSON
JONATHAN P. NOVAK
Attorneys
Diversion & Regulatory Litigation
Office of Chief Counsel

Date: October 31, 2012

CERTIFICATE OF SERVICE

I hereby certify that on the date signed below, I caused the original and two copies of the foregoing **GOVERNMENT'S PREHEARING STATEMENT**, to be hand delivered and faxed to the DEA Office of the Administrative Law Judges, and I caused a copy of the same to be sent, *via e-mail* to counsel for Respondent at the following addresses:

Phil Perry
Allen M. Gardner
Nathan H. Seltzer
Latham & Watkins LLP
555 Eleventh Street, NW
Suite 1000
Washington, DC 20004-2232
Fax: 202.637.2201
Email: Phil.Perry@lw.com
Allen.Gardener@lw.com
Nathan.Seltzer@lw.com

David S. Weinstein
Clarke Silverglate P.A.
799 Brickell Plaza
Suite 900
Miami, Florida 33131
Fax: 305-377-3001
Email: DWeinstein@cspalaw.com

30.1.12
Date

Signature

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UNITED STATES DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

IN THE MATTER OF WALGREEN, CO.	DOCKET NO. 13-01 ADMINISTRATIVE LAW JUDGE JOHN J. MULROONEY, II

GOVERNMENT'S SUPPLEMENTAL PREHEARING STATEMENT

Scott Lawson
Jonathan Novak
Attorneys
Diversion & Regulatory Litigation
Office of Chief Counsel
8701 Morrissette Drive
Springfield, VA 22152
Tel: 202.307.8038
Fax: 202.307.4946

Date: December 7, 2012